Exhibit 9-1

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CLERK OF COURT

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES, INC. Plaintiff, v. **MALLINCKRODT ARD, INC.,** ***Formally known as*** **QUESTCOR PHARMACEUTICALS, INC.;** **MALLINCKRODT PLC;** **EXPRESS SCRIPTS HOLDING COMPANY;** **EXPRESS SCRIPTS, INC.;** **CURASCRIPT, INC.,** ***doing business as*** **CURASCRIPT, SD;** **PRIORITY HEALTHCARE CORP. AND PRIORITY HEALTHCARE DISTRIBUTION, INC.,** ***doing business as*** **CURASCRIPT SD AND CURASCRIPT SPECIALTY DISTRIBUTION SD,** ***respectively*****;** **ACCREDO HEALTH GROUP, INC.;** **UNITED BIOSOURCE CORPORATION;** ***and*** **JAMES A. TUMLIN. M.D.** Defendants.	**DOCKET NO. _____** DIVISION: **JURY TRIAL DEMANDED**

COMPLAINT

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COMPLAINT

Acument Global Technologies, Inc. ("Acument" or "Plaintiff") alleges as follows:

NATURE OF THE CASE

1. Acument brings this action to challenge the anti-competitive, unfair and deceptive scheme and conspiracy by Defendants, Mallinckrodt ARD Inc., formally known as Questcor Pharmaceuticals, Inc. ("Questcor") and its parent company, Mallinckrodt plc (collectively "Mallinckrodt"), as well as Mallinckrodt's exclusive agent for the delivery of its principal product, Express Scripts Holding Company ("ESHC") and Express Scripts, Inc. ("ESI")(collectively "Express Scripts"), including their wholly-owned subsidiaries, CuraScript, Inc., doing business as CuraScript SD, formerly known as CuraScript Pharmacy, Inc., ("CuraScript"), Priority Healthcare Corp. and Priority Healthcare Distribution Inc. ("Priority") also doing business as CuraScript SD (collectively, "CuraScript SD"), Accredo Health Group, Inc. ("Accredo"), and United BioSource Corporation n/k/a United BioSource LLC ("UBC")(collectively referred to as the "Express Scripts Entities") and one of Mallinckrodt's principal medical provider advocates, James A. Tumlin, M.D. ("Dr. Tumlin").

2. The anticompetitive scheme alleged herein sought to maintain and enhance Mallinckrodt's monopoly power in the U.S. market for adrenocorticotropic hormone (ACTH) drugs, and to fix the prices of ACTH drugs, in violation of the Tennessee antitrust laws. The Defendants named herein conspired and agreed with one another to defraud patients and payors, like Acument, by overcharging them for Acthar when there existed other equally or more efficacious, and cheaper, treatments for the disease states for which Acthar was marketed, prescribed and sold.

3. Mallinckrodt manufactures, markets, distributes and sells H.P. Acthar, NDC Nos. 63004-8710-01 and 63004-7731-01 ("Acthar"). Acthar is the only therapeutic ACTH product sold in the United States. Mallinckrodt is the sole provider in the U.S. of approved ACTH drugs. Thus, Mallinckrodt is a monopolist.

4. Mallinckrodt acquired its ACTH monopoly in 2001 when Questcor purchased Acthar from Aventis for $100,000. By 2014, when Mallinckrodt purchased Questcor, the value of that Acthar monopoly was $5.9 billion—the price paid for the single-product company.

5. This case does not seek to challenge the lawfulness of Mallinckrodt's monopoly. It seeks to challenge the lawfulness of Mallinckrodt's exercise of its monopoly power, in conjunction with its co-conspirators, by taking actions to maintain and enhance that monopoly power, and to fix prices, in violation of the Tennessee antitrust laws.

6. The Tennessee antitrust laws permit indirect purchasers like Acument to recover for such unlawful conduct.

7. The issue is not whether Mallinckrodt possessed monopoly power in the ACTH market. It is whether Mallinckrodt's actions in 2007 to contract with the agent of its leading customers, Express Scripts, in order to limit distribution, and to raise and fix the prices of Acthar above competitive levels, was unlawful.

8. Years later, in 2013, armed with this enhanced monopoly power through its direct agreements with Express Scripts, Mallinckrodt then further enhanced its monopoly power by acquiring the only competitive product in the marketplace, Synacthen. Express Scripts did not push back on behalf of its clients, the third party payors who, like Acument, pay vast sums for specialty medications for their employees and their families. Express Scripts brought no pressure against Mallinckrodt to either bring Synacthen to market or to lower Acthar prices.

Instead, Express Scripts continued to work with Mallinckrodt to preserve and protect the Acthar monopoly and price fixing scheme.

9. Acthar is a "specialty pharmaceutical". It is not sold in retail pharmacies, nor is it distributed through wholesalers to retail pharmacies, as with most prescription drugs. Instead, it is distributed only through "specialty pharmacy distributors".

10. While there are dozens of specialty pharmacy distributors in America, one of the largest is Express Scripts' CuraScript, including CuraScript SD, which Express Scripts has owned since 2004.

11. In 2007, Mallinckrodt decided to embark on a self-described "new strategy", and it changed its distribution of Acthar as part of such strategy. Express Scripts was critical to the success of this new strategy. Rather than continue to distribute Acthar to the existing distribution network available for specialty drugs, Mallinckrodt chose to limit Acthar distribution exclusively through Express Scripts' CuraScript SD. In effect, Mallinckrodt contracted with the agent of its leading customers in order to create an exclusive arrangement whereby both companies would share the financial rewards of the Acthar monopoly and resulting price fixing agreement.

12. As described more fully below, this "new strategy" involved the implementation of actual, written agreements, signed by both Mallinckrodt and Express Scripts, by which Express Scripts was granted exclusive specialty distribution of Acthar in exchange for its agreement to allow Mallinckrodt to raise the prices of Acthar to exorbitant, non-competitive levels.

13. Immediately after signing the exclusive agreements in the summer of 2007, Mallinckrodt and Express Scripts jointly agreed in writing to raise and fix the average wholesale prices ("AWPs") paid for Acthar by employers like Acument from $2,062.79 per vial to

$29,086.25, more than a 1,300% increase in the cost of Acthar in the span of a month.

14. As a result, this exclusive arrangement, Mallinckrodt was able to charge inflated prices for Acthar to all direct purchasers of Acthar, through Express Scripts acting as the "pharmacy benefits manager" or "PBM" of such direct purchasers, as well as all indirect purchasers of Acthar, like Acument, who purchase Acthar through a different PBMs.

15. While Acument initially utilized Express Scripts as its PBM when its beneficiary was started on Acthar in 2011, it switched to CVS/Caremark in 2015-2016, when it began being charged by Defendants for the Acthar.

16. In December 2015 Acument started paying for Acthar. Acument was charged a price based upon the AWP for Acthar. By that time, Mallinckrodt and Express Scripts had jointly agreed to raise the AWP for Acthar to over $40,000.00. In other words, these Defendants jointly agreed to raise the price paid by patients and payors, like Acument, from $40.00 in 2001 to over $40,000.00 in 2015. Working with their provider partner, Dr. James Tumlin, the Defendants collectively were able to charge patients and payors in Tennessee this inflated AWP, and were able to reap monopoly profits from their scheme.

17. In the case of Acument, over the 13-month period between December 2015 and December 2016, Acument and its beneficiary spent $894,617.75 for just 13 prescriptions of Acthar given to the spouse of one of Acument's employees. The employee's co-pay was $200.00 per prescription, meaning the employee paid $2,600.00 for the 13 doses. Acument paid the full balance, $892,017.75.

18. Acument brings this lawsuit to obtain declaratory and injunctive relief, in order to have the conduct of Defendants declared unlawful and to enjoin such unlawful conduct going forward to arrest the scheme and to prevent a recurrence of the overcharges. Acument also seeks

to recover money damages for its past overcharge payments, including "the full consideration or sum paid" by it for Acthar, pursuant to Tennessee Trade Practices Act ("TTPA"), Tenn. Code. § 47-25-106. Acument seeks recovery of its ascertainable loss of money expended in the payments for Acthar pursuant to Tennessee Consumer Protection Act ("TCPA"), Tenn. Code. § 47-18-109(a)(1). Acument seeks compensatory damages pursuant to the Tennessee common law of unjust enrichment, fraud, conspiracy to defraud and aiding and abetting. Finally, Acument seeks punitive damages for the Defendants' willful, outrageous and reckless conduct.

JURISDICTION AND VENUE

19. This Court has personal jurisdiction over the parties because most of the Defendants are located in and conduct substantial business in this State, are registered to do business in this State, have had systematic and continuous contacts with this State, and have agents and representatives that can be found in this State.

20. Venue is proper in this Court because Defendants CuraScript SD, Accredo and UBS are all situated in this County, and the other Defendants transact business in this County. Venue is also proper pursuant to TTPA § 47-18-109(a)(2) because the alleged unfair or deceptive acts or practices took place, are taking place, and will continue to take place in this County unless abated by the declaratory and injunctive relief requested herein is granted.

21. Acthar is sold in both interstate and intrastate commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had a substantial effect upon, the intrastate commerce of Tennessee.

22. In fact, the Defendants' contacts both with and within this State have been to such degree that the anticompetitive conduct alleged herein has affected Tennessee trade and commerce to a substantial degree, as described more fully below.

THE PARTIES

PLAINTIFF

23. Acument Global Technologies, Inc. ("Acument") is a Delaware corporation which employs individuals in 12 locations in the United States and Mexico, including in Spencer, Tennessee. Specifically, Acument has a corporate office located 502 Industry Drive, Spencer, Tennessee 38585.

24. Acument provides healthcare benefits to its employees through Blue Cross Blue Shield of Michigan ("BCBS Michigan"). In 2011, BCBS Michigan provided prescription drug benefits to Acument through its contracted PBM, Medco. In July 2011, Medco was acquired by Express Scripts, along with Accredo and United BioSource. As of that date – which was the same year that Acument had one of its beneficiaries placed on Acthar – Express Scripts was Acument's PBM. In 2015 and 2016, Acument contracted with a different PBM, CVS/Caremark.

25. The spouse of one of Acument's employees [hereinafter referred to as the "Patient" to protect the patient's HIPAA privacy rights] was treated by Defendant Dr. James A. Tumlin, of Chattanooga, Tennessee, during the time that Dr. Tumlin was serving as a paid consultant for Mallinckrodt. Specifically, in 2011, Dr. Tumlin prescribed Acthar to the Patient, but Acument was not charged for it. Then, between December 2015 and December 2016, Dr. Tumlin again prescribed Acthar to the Patient. This time, Acument was charged and it paid $894,617.75 for Acthar at cost of $68,816.75 per prescription, while the Patient paid co-pays of $200 per prescription at a total cost of $2,600. Acument paid the inflated price for Acthar as set by Mallinckrodt and Express Scripts and as charged by Dr. Tumlin. As explained more fully herein, these exorbitant charges were based upon the inflated AWPs established by Mallinckrodt and Express Scripts, causing Acument to suffer antitrust injury.

DEFENDANTS

26. Questcor Pharmaceuticals, Inc. ("Questcor") was acquired by Mallinckrodt on August 14, 2014 for $5.9 billion, after Questcor had paid only $100,000 for Questcor's lone product Acthar 13 years earlier.

27. Following the acquisition, Questcor became a wholly-owned subsidiary of Mallinckrodt and its name was changed to Mallinckrodt ARD Inc ("Mallinckrodt ARD"). Defendant Mallinckrodt ARD is a biopharmaceutical company incorporated in California, with offices located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042, 26118 Research Road, Hayward, California 94545 and 1425 U.S. Route 206, Bedminster, New Jersey 07921.

28. At the time of the Mallinckrodt acquisition of Questcor in 2014, Mallinckrodt ARD's only product sold in the United States was Acthar. Since the acquisition, Mallinckrodt has continued to manufacture, distribute, market and sell Acthar directly to patients, exclusively through Express Scripts, by a program known as the "Acthar Support and Access Program" ("ASAP") described more fully below.

29. Defendant Mallinckrodt plc ("Mallinckrodt plc") is an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, the Causeway, Staines-upon-Thames, Surrey, TW18 3 AG.

30. Where appropriate, Mallinckrodt plc and Mallinckrodt ARD are collectively referred to as "Mallinckrodt".

31. Defendants Express Scripts, Inc. ("ESI") and Express Scripts Holding Company ("ESHC") are Delaware corporations with their principle executive offices located at 1 Express Way, Saint Louis, Missouri 63121 and Century Center Drive, Memphis, Tennessee (collectively,

"Express Scripts").

32. Defendants Priority Healthcare Corp. and Priority Healthcare Distribution Inc. ("Priority") d/b/a CuraScript SD (collectively, "CuraScript SD"), are wholly-owned subsidiaries of Express Scripts. Priority/CuraScript SD has maintained corporate offices at 1680 Century Center Parkway, Memphis, Tennessee 38134-8827.

33. Defendant CuraScript, Inc., d/b/a CuraScript SD, f/k/a CuraScript Pharmacy, Inc., is a wholly-owned subsidiary of Express Scripts. ESHC acquired CuraScript in January 2004. Its operation was expanded when ESHC acquired Priority in October 2005 and combined it with CuraScript. The combined Priority and CuraScript SD (collectively "CuraScript") became one of the nation's largest specialty pharmacy and distribution companies with more than $3 billion in annual revenue.

34. CuraScript is an Indiana corporation with corporate offices located at 255 Technology Park, Lake Mary, Florida 32746. This is the same Florida address patients are required to mail any revocation of the broad authorization granted by patients to Mallinckrodt and Express Scripts via the Acthar Start Form (*see*, Exhibit "A" hereto). CuraScript has been Mallinckrodt's exclusive specialty pharmacy distributor for Acthar since 2007.

35. Significantly, Express Scripts chose to end this exclusive distribution relationship in September 2017 only after it was sued for antitrust in 2017 by the City of Rockford, Illinois.

36. Defendant Accredo Health Group, Inc. ("Accredo") is a wholly-owned subsidiary of Express Scripts. Accredo became a wholly-owned indirect subsidiary of Medco Health Solutions, Inc. ("Medco") on August 18, 2005, months before Express Scripts acquired Priority, and then became part of Express Scripts when Express Scripts acquired Medco in 2012. At that time, Medco became a wholly owned subsidiary of ESHC.

37. Accredo is a Delaware corporation with its corporate headquarters at 1640 Century Center Parkway, Memphis, Tennessee 38134 and a business location at 201 Great Circle Road, Nashville, Tennessee 37228. Accredo also has operations in Warrendale, Pennsylvania; Corona, California; Greensboro, North Carolina; Orlando, Florida; and Indianapolis, Indiana.

38. Defendant United BioSource Corporation n/k/a United BioSource LLC ("UBC") is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422 and a business location at 1670 Century Center Drive, Memphis, Tennessee. UBC was a wholly-owned subsidiary of Express Scripts from 2012, when it was acquired by Express Scripts as part of the Medco merger, until November 2017, when Express Scripts announced that it sold UBC to Avista Capital Partners, a private equity firm.

39. UBC is a wholly owned subsidiary of United BioSource Holdings, Inc., the interests of which are held by and through various privately held intermediary entities, which are ultimately owned by private investment funds sponsored by and/or affiliated with Avista Capital Partners and as-yet-unknown individuals associated with Avista Capital Partners.

40. UBC is described as Mallinckrodt's "agent" on the Acthar Start Form (*see* Exhibit "A" hereto) which Mallinckrodt employs exclusively to operate the ASAP program and to manage the Express Scripts Entities' exclusive distribution, sales and reimbursement of Acthar by its 3 operating arms, CuraScript, Accredo and Express Scripts.

41. UBC provides customer support and reimbursement support for Acthar as the "HUB" of Express Scripts' three operating arms, CuraScript (providing specialty distribution services), Accredo (providing specialty pharmacy services) and Express Scripts (providing pharmacy benefit management services).

42. Defendant James A. Tumlin, M.D. ("Dr. Tumlin") is a physician who specializes

in nephrology and is associated with Nephrology Associates of Chattanooga located at 2300 E. 3rd Street, Chattanooga, Tennessee.

43. Dr. Tumlin is founder and medical director of Southeast Renal Research Institute (SERRI) since 2005. The institute was brought to Chattanooga in 2008 and merged with Nephrology Associates' Research Department.

44. Dr. Tumlin is one of Defendant Mallinckrodt's principal medical providers and key opinion leaders ("KOLs"). He has been paid hundreds of thousands of dollars for his work on behalf of the company.

45. Dr. Tumlin was the treating physician for one of Acument's employee's spouse.

46. As stated in Paragraph 1 above, ESI, ESHC, CuraScript, Accredo and UBC are collectively referred to herein as "Express Scripts".

47. Mallinckrodt and Express Scripts are collectively referred to herein as "Defendants", as appropriate.

48. The Defendants' acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

FACTUAL BACKGROUND

49. "I have a Cadillac in my refrigerator." That is how one Acthar patient named Sharon Keller described an unused 5-ml vial of the medication sitting in her kitchen refrigerator.

50. The tale of how a 65 year-old brand medication could rise in price from $40 per vial in 2001, to $40,840.80 per vial by 2015, raising that value of the brand from $100,000 to $5.9 billion, is a story of perhaps the most egregious fraud and monopolistic conduct in U.S.

history by a prescription drug company.

51. The issue in this case is how Mallinckrodt achieved such a startling outcome.

History of Acthar Development, Distribution and Pricing

Acthar Development

52. Acthar was approved by the Food and Drug Administration ("FDA") in 1952 for over fifty conditions, ranging from alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. Over time, with additional evidence-based requirements for prescription drugs, the list was winnowed to the fewer, present-day nineteen indications.

53. Acthar is adrenocorticotropic hormone ("ACTH"), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at the time it was developed. Acthar was developed by Armour Pharmaceutical Company. As described by the Seventh Circuit in *Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 145-46 (7th Cir. 1960):

> In a human being, . . . (ACTH) appears in the anterior lobe of the pituitary gland located at the base of the brain. When the human body is under stress or attacked by certain diseases, control centers in the brain excite the pituitary, and the pituitary secretes ACTH. In the blood stream the ACTH thus secreted is carried to the adrenal glands situated in the human body above the kidneys. As the ACTH hits the outer wall of the adrenal glands, it stimulates the adrenals to produce a set of chemical substances such as steroids, including the hormones, cortisone and hydrocortisone.
>
> The cortisone hormones then act in the tissues of the body to suppress inflammations and allergic reactions. ACTH thus is used to relieve such conditions as rheumatoid arthritis and allergies. ACTH does not, itself, directly attack disease. However, it stimulates the adrenals which produce more than twenty-eight steroids, and these hormones attack the diseased tissues. When the human body itself does not supply sufficient ACTH, pharmaceutical ACTH can fill the gap.

54. By the 1960s, injectable ACTH medications faced a variety of competing products. *See id.* at 145 ("Both Armour and Wilson manufacture and sell gelatin-ACTH preparations . . . . Gelatin-ACTH now constitutes more than 80% [o]f all forms of ACTH products sold by Armour and Wilson. Other companies . . . produce similar products").

55. For the majority of the drug's lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved. That factor tended to limit the market for Acthar to treating infantile spasms ("IS") which was originally an "off-label" indication. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at $40 per vial and accounted for less than a million dollars of revenue for Aventis Pharmaceuticals, Inc. ("Aventis"), the then-owner.

56. In 2001, Questcor acquired Acthar from Aventis for only $100,000, but in 2014 Mallinckrodt acquired Questcor for $5.9 billion.

57. Acthar's value was limited because it was the "gold standard" for treating only one condition, infantile spasms ("IS"). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. In 2010, the IS indication was approved by the FDA, and orphan drug status was granted.

Acthar Distribution: Mallinckrodt Adopts a "New Strategy" to Restrict Acthar Distribution to Maintain and Enhance its Monopoly Power over Acthar

58. Acthar is a specialty pharmaceutical distributed directly to patients, like the beneficiary Patient of Acument in this case.

59. For decades, Acthar was distributed to any doctor, hospital, wholesaler or specialty pharmacy who requested the drug to treat seriously ill patients. After Questcor acquired the rights to Acthar, it initially maintained that broad distribution network.

60. However, on July 2, 2007, Mallinckrodt restricted its distribution from three wholesalers, termed Wholesalers "A", "B", and "C" in its 2007 10-K, to just Express Scripts, the agent of its largest customers. Mallinckrodt's announcement stated, **"[e]ffective August 1, 2001, Acthar…will be available exclusively through Specialty Pharmacy Distribution**. Acthar Gel will no longer be available from traditional pharmaceutical wholesalers or retail pharmacies." *See* July 2, 2007, "Urgent Product Alert H.P. Acthar Gel" (attached to the Complaint at Exhibit "B"). All distribution would now be done exclusively through CuraScript. Mallinckrodt directed that "all new Acthar Gel prescriptions should be submitted to the Acthar Support & Access Program." *Id.* From that point on, all aspects of Acthar distribution were handled by the Express Scripts Entities.

61. The goal of this "new strategy" was to lock patients into receiving Acthar through one distribution channel controlled by Mallinckrodt and the Express Scripts Entities, and to ensure prescription distribution and payment through one source, Express Scripts Entities. Mallinckrodt has maintained this exclusive arrangement with the Express Scripts Entities since 2007 up through at least September 2017 when the Express Scripts Entities claim that CuraScript SD "is no longer the exclusive distributor of Acthar".

62. Of course, Mallinckrodt and the Express Scripts Entities were sued for antitrust in April 2017 by the City of Rockford, and thus apparently only ended the "exclusive distribution" aspect of their unlawful arrangement in response to such claims. However, other aspects of their unlawful arrangement remain, including their use and employment of the ASAP, which continues to be operated by their self-described "HUB", UBC, as described more fully below. As a result, declaratory and injunctive relief continues to be required in this case to eradicate the harmful effects of Defendants' unlawful conduct moving forward.

63. Mallinckrodt's "new strategy" was the brainchild of Greg LaPointe, a member of the Questcor Board of Directors and former Chief Executive Officer of Sigma-Tau Pharmaceuticals, the largest shareholder in Questcor in the early 2000s, and Steve Cartt, Questcor's Chief Operating Officer and Executive Vice-President in charge of sales and marketing of Acthar. LaPointe also served as a member of the Corporate Council of the National Organization for Rare Diseases ("NORD"), which served as an important player in Mallinckrodt's scheme to minimize resistance and pushback by patients and physicians to Acthar's higher prices by serving as a leading distributor of free Acthar supplied by Mallinckrodt to patients who could not afford to pay the newly established monopoly prices.

64. LaPointe and Cartt approached then-Questcor Board member Don Bailey to garner his support for the new strategy. Their "offline" discussions did not sit well with Questcor's President and CEO at the time, James L. Fares.

65. In February 2005, Mr. Fares was appointed President and CEO of Questcor by the Board of Directors. According to Albert Hanson, the Chairman of the Board, "the Board sought an accomplished pharmaceutical executive with substantial expertise in selling and marketing pharmaceutical products." Chairman Hanson further explained the selection of Feres as follows:

> [T]he Board assessed each candidate's track record and capability to think creatively about Questcor's business. Such skills are critical in developing and executing a successful long-term strategy for a specialty pharmaceutical business. We looked for a talented executive who understood the specialty pharmaceutical market and had demonstrated the leadership skills necessary to create shareholder value. We believe that in Jim Fares we have found that executive. His successful track record in sales, marketing, business development, and general management, coupled with his energy and enthusiasm for pharmaceuticals, convinced us that we had found the right individual to lead Questcor.

66. Prior to joining Questcor, Feres held senior management positions at Merck,

Athena Neurosciences and Elan Pharma. He founded and served as Sr. Vice President of Commercial Operations at Xcel Pharmaceuticals from 2001 – 2003. In his last position, he served as CEO and President of FGC Pharm/Novella Neurosciences.

67. Feres resigned in May 2007. He was replaced by Don Bailey, whom the Board first appointed as Interim President, but then elevated to full-time President and CEO in conjunction with Questcor's adoption of the new strategy.

68. Mallinckrodt signed contracts with the Express Scripts Entities in late June 2007.

69. Shortly thereafter, in July 2007, three Board members resigned, including the Chairman Albert Hanson.

70. Questcor's Sr. Vice President of Strategic Planning and Communications, Eric Liebler, also quit. Liebler quit less than a year after being hired. He quit just three weeks after the "new strategy" was announced.

71. In spite of this mass exodus of leading executives and Board members, Mallinckrodt chose to adopt a controversial "new strategy" to allow Mallinckrodt to "optimize" its monopoly status for Acthar, especially in the IS market.

72. The self-described "orphan drug strategy" worked as follows: despite the fact that Acthar was an older drug, Mallinckrodt would "re-launch" Acthar with a new, limited distribution system and a substantially higher price, to make it appear as if Acthar were a new product being launched as the only product indicated for IS, an off-label indication at the time.

73. The IS market was a captive market involving a life-threatening disease afflicting infant children. Like other debilitating or life-threatening, orphan conditions, for which there was only one, sole-source drug treatment, IS presented Mallinckrodt with an opportunity to leverage its monopoly power against a particularly fragile, powerless patient population in an

extremely narrow market.

74. As a result, Mallinckrodt predicted that the IS market would likely be able to absorb a much higher price with little resistance. In contrast, Mallinckrodt feared that the market for drug treatments of other disease states, such as the MS market, would not tolerate such a higher price. Nevertheless, Mallinckrodt only viewed the anticipated resistance to higher prices by patients and payors as a challenge to be overcome.

75. Mallinckrodt overcame such challenge in at least two ways after the launch of the new strategy in August 2007: (1) conspiring and agreeing with the Express Scripts Entities to eliminate competition, enhance Mallinckrodt's monopoly power, and to raise and fix the prices for Acthar; and (2) engaging leading medical providers, described as "key opinion leaders" or "KOLs", like Defendant Dr. Tumlin, in the treatment of the various disease states for which Acthar was narrowly indicated to ensure that Acthar was prescribe as a primary course of treatment.

76. The new pricing established by Mallinckrodt and Express Scripts was only limited by what these companies predicted that payors, like Acument, would be willing to bear.

77. Mallinckrodt Executive Vice-President, Steve Cartt, admitted "'[w]e did some market research,' . . . [t]alking to physicians and others about pricing 'gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would pay' . . . . 'The reality was better than we expected.'"[1]

Acthar Distribution: the Acthar Support & Access Program and Express Scripts' "HUB"

78. One of the primary means by which Defendants manifested their unlawful scheme was through a program known as the "Acthar Support & Access Program" or "ASAP." This

[1] Milt Freudenheim, *Benefit Managers Profit by Specialty Drug Rights*, New York Times, C1, April 19, 2008 (titled The Middleman's Markup in New York Print Ed.)(hereinafter, "*Fruedenheim*").

program is structured so that Mallinckrodt ships Acthar directly to patients and receives payment directly from the associated third party payors.

79. Once the patient (or their physician) contacts Mallinckrodt for a prescription of Acthar, they are directed to UBC. Otherwise, patients and/or their providers contact UBC directly, as directed by the Acthar Start Form at attached as Exhibit "A" hereto. UBC then serves as the "HUB" for Mallinckrodt and the Express Scripts Entities. UBC also serves as the primary interface with other PBMs, like CVS/Caremark utilized by Acument in 2015-2016 when it paid for Acthar. As the HUB, UBC confirms the prescription by the provider with a specialty pharmacy, whether Accredo or some other specialty pharmacy. UBC then confirms the patient's insurance coverage or other source of payment, whether with Express Scripts, CVS/Caremark or some other PBM or insurer. UBC then arranges for Acthar to be delivered directly to the patient by CuraScript.

80. This process is laid out in the form provided by Mallinckrodt, the "Acthar Start Form" (Exhibit "A" hereto). The form requires patient, physician/pharmacy and payor authorization before Mallinckrodt ships the Acthar to patients via CuraScript. At no point is any Express Scripts Entity at risk, as Mallinckrodt ensures its payment at each level of the process.

81. The Acthar Start Form consists of 3 sections: (1) a section requiring signature by the "HCP" (or health care professional); (2) a patient authorization requiring signature by the "patient or legal representative"; and (3) information concerning Acthar indications and usage. The required signature of the patient authorizes "Mallinckrodt **and its agents**" to do a number of things in relation to the prescription and distribution of Acthar. It further authorizes Mallinckrodt and its agents, "including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support Access

Program on behalf of Mallinckrodt (collectively, 'Designated Parties')" to provide Acthar and receive payment, among other things.

82. Specifically, the patient authorizes Mallinckrodt, UBC, "or any other operator" of ASAP on behalf of Mallinckrodt, referred to as Mallinckrodt's "Designated Parties", "to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training." In other words, the patient directly authorizes Mallinckrodt and its agents to ship Acthar to them directly via CuraScript, and authorizes payment by both the patient and any third party payor prior to obtaining the medication. So, the patient authorizes Express Scripts to bill the payor for Acthar.

83. Similarly, the physician must "authorize[ ] United BioSource Corporation ("UBC"), the current operator of the Acthar Support and Access Program ("Program"), and other designated operators of the program, to perform a preliminary assessment of benefit verification for this patient…". The physician also "agree(s) that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy."

84. The interaction of all 4 elements of the Express Scripts Entities' functions on behalf of Mallinckrodt are described below.

85. Express Scripts is one of the largest PBMs in the United States.

86. PBMs pool together the purchasing power of all their health plan clients to get greater volume discounts and rebates from drug manufacturers than a single plan could do on its own.

87. Express Scripts negotiates with pharmaceutical manufacturers for both discounts

and rebates on prescription drugs. Express Scripts then offers its health plan customers both discounts and rebates on such prescription drugs.

88. In terms of the financial benefits to Express Scripts' health plan customers, drug discounts and rebates are the same. Paying rebates to a plan for a prescription drug is functionally equivalent to charging the plan a reduced price for that drug (a rebate is simply a retroactive discount on the price of the drug).

89. As a large purchaser of prescription drugs, aggregating the purchasing power of its many health plan clients, Express Scripts has a financial advantage in its negotiations with pharmaceutical manufacturers that arises from its market power.

90. The "family" of Express Scripts Entities does more than simply process claims for prescriptions filled at pharmacies for their plan customers. In addition to "retail pharmacy claims processing, formulary management, utilization management and home delivery pharmacy services", the Express Scripts Entities offer "specialty services that deliver . . . high-cost injectable, infused, oral or inhaled drugs," and "compliance programs, . . . drug therapy management programs, [] data analysis, and [] distribution services."[2] Acting "either directly or through its subsidiaries", including the Express Scripts Entities, Express Scripts acts as a direct pipeline from a pharmaceutical manufacturer to the patient, facilitating the direct distribution of a prescription drugs from the factory to the patient's home.

91. Express Scripts is able to act as a manufacturer's direct distributor of specialty drugs to patients because it provides what it calls "integrated specialty services." (emphasis in original).[3] As one Express Scripts' executive put it "we're family." These integrated services

[2] Express Scripts Holding Company Annual Report on Form 10-K for the Fiscal Year Ending December 31, 2012.

[3] https://curascriptsd.com/corporate-overview

include a PBM (Express Scripts), a specialty pharmacy distributor (CuraScript), and a specialty pharmacy provider (Accredo).

92. Express Scripts coordinates all of these functions through its so-called pharmaceutical support services unit, UBC. UBC acts as a "'hub,' that serves as a centralized point of contact for [] patients [] and prescribers"[4] by "[w]orking hand-in-hand with Express Scripts' specialty pharmacy and specialty distribution organizations, Accredo and CuraScript [],"[5] to coordinate delivery of and reimbursement for specialty pharmaceuticals.

93. In total, UBC operates "an integrated service model that involves UBC . . . manag[ing] multiple system applications that support one product. [UBC's] services include the UBC coordinating center, nurse coordination . . . product fulfillment through Accredo and wholesale fulfillment through CuraScript[]. When a patient is prescribed [a specialty] medication, the doctor sends a referral to the Reimbursement Hub. [UBC's] team serves as the liaison among doctors, patients, and insurance companies as [UBC] . . . navigate[s] the coverage process. [UBC] . . . ensure[s] a smooth transition from enrollment through shipment of the medication."

94. Part of the reimbursement hub process is coordination with Express Scripts' CuraScript, which acts as an "integrated delivery network" connecting patients to manufacturers through "end-to-end distribution services."[6] Simply put, CuraScript is similar to a FedEx, DHL, or UPS for specialty prescription drugs. CuraScript advertises that it is "recognized by the manufacturing community as [] a reliable partner in the management of brands" through

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[4] http://www.ubc.com/services/loyalty/reimbursement-patient-assistance

[5] http://www.ubc.com/about/about-ubc

[6] https://curascriptsd.com/Rare-Disease-Specialty-Distribution-Program

CuraScript's "integrated specialty services," which deliver medications to patients "alongside sister organizations Accredo and UBC."[7]

95. To facilitate these end-to-end distribution services, UBC coordinates CuraScript's activities with Accredo, which provides so-called specialty pharmacy services. By acting as the hub, UBC ensures that a patient whose pharmacy benefits are managed by Express Scripts can get a specialty medication delivered to him or her by coordinating direct shipment through CuraScript and Accredo and direct payment through Express Scripts. "As one UBC executive has explained "if UBC is the Hub and Accredo is the [specialty pharmacy] . . . we can send the patient's prescription over to Accredo, and they will not have to duplicate any of our efforts, which another pharmacy would be compelled to do because of risk. Accredo trusts us."

96. Accredo provides specialty pharmacy and related services for patients with certain complex and chronic health conditions. Accredo's staff is comprised of a team of specialty-trained pharmacists, nurses, patient care advocates, social workers and insurance coordinators whom, among other things, "handle everything about" a patients' medications and/or specialty therapy.

97. Along with UBC, Accredo provides: (a) support to orphan and ultra orphan patient populations; (b) HUB employees to navigate insurance requirements, like prior authorizations, for patients and prescribers; (c) clinicians who are available 24/7 to address patient concerns and provide guidance on mitigating adverse events; (d) reimbursement HUB specialists to steer patients to funding solutions, and (e) an integrated solution allowing patients to start therapy twice as fast.

98. The Acument patient at issue dealt with CVS Caremark Specialty for their fulfillment of Acthar. It is believed, and therefore averred, that UBC coordinated the shipment

[7] https://curascriptsd.com/supplier-relations

of Acthar directly to the Patient via the same integrated "hub" network with the lone exception being that Acument's payment was made to its PBM, CVS Caremark, before being routed to Mallinckrodt. In all other respects, the operations of the hub were the same, with the Acthar being shipped by Express Scripts' CuraScript pursuant to the same 2007 exclusive agreement .

99. In simple terms, through UBC's coordination with Accredo, CuraScript, and Express Scripts, Express Scripts delivers a prescription drug directly from the manufacturer to the patient, removing all impediments to delivery and payment, whether medical, logistical or financial.

100. With respect to Acthar, Mallinckrodt has a contract with UBC to coordinate the delivery of Acthar through what it has called the ASAP Program. Beginning with its July 2, 2007 announcement, Mallinckrodt directed physicians to prescribe Acthar through the ASAP program. *See* Exhibit "B". In this announcement, Mallinckrodt directed physicians that "all new Acthar [] prescriptions should be submitted to the [ASAP program]." Prescriptions are submitted to the ASAP program through the "Acthar Start Form." *See* Exhibit "A". This form authorizes UBC to coordinate reimbursement with Express Scripts and direct the prescription to a "designated specialty pharmacy." This designated specialty pharmacy is Accredo. Accredo dealt with the Acument patients in 2015. Part of UBC's activities involve coordinating the shipment of Acthar from CuraScript through Accredo to the patient. Indeed, in order to revoke UBC's authorization to perform these services, the patient must mail a letter to CuraScript's address in Florida. It is believed and therefore averred that Acument's patient provided a similar authorization to UBC for shipment from CuraScript.

101. The Acthar direct distribution arrangement between Mallinckrodt and Express Scripts is illustrated in the following two figures. In Figure 1, the product distribution

arrangement is as follows.

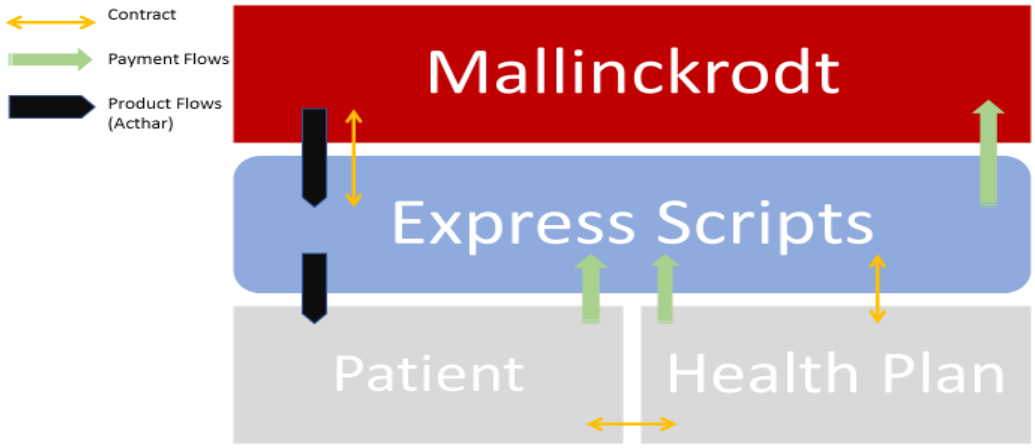

Figure 1

102. Figure 2 below illustrates how Acthar is prescribed, authorized, distributed and paid for through Express Scripts. Although these payments pass through Express Scripts, payment flows and products flows are ultimately aligned between Mallinckrodt and UBC, Express Scripts' reimbursement hub, through a contract with Mallinckrodt to operate the ASAP program, which confirms the medical necessity of the prescription (by Accredo or other specialty pharmacy), arranges for payment (by PBMs like Express Scripts and CVS Caremark) and then for shipment and billing (by CuraScript).

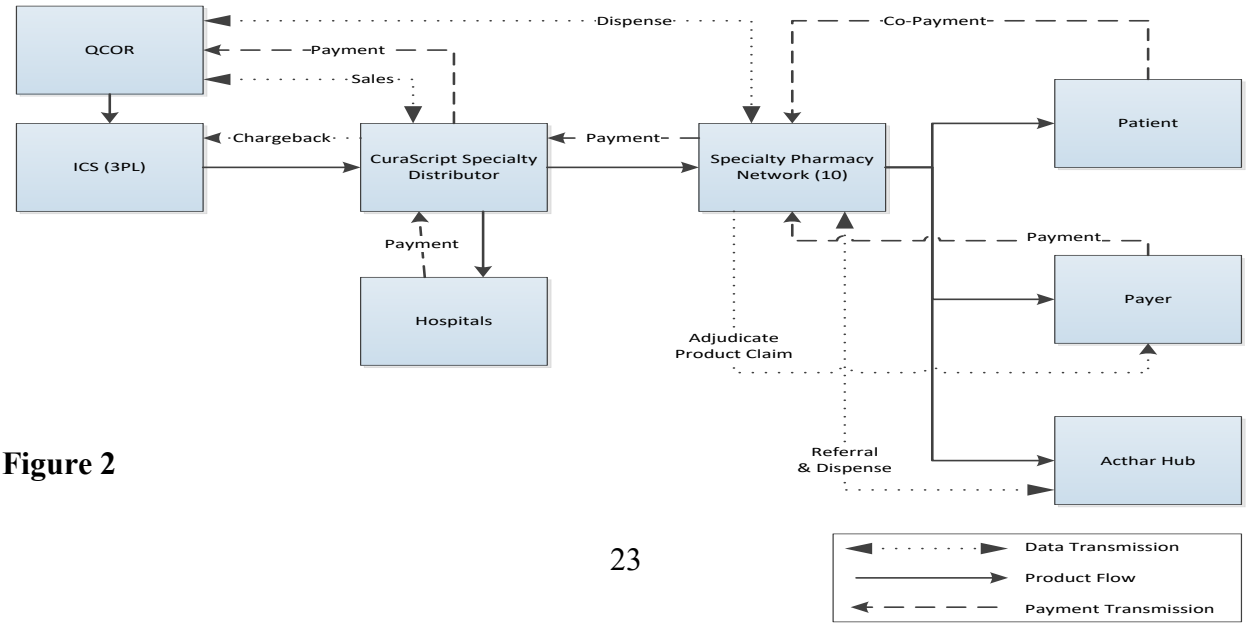

Figure 2

103. Since the launch of the new strategy, CuraScript has contracted directly with Mallinckrodt to ship Acthar. Through such contractual arrangement, Acthar travels from Mallinckrodt directly to the patient, and payments are channeled directly back to Mallinckrodt.

104. As depicted above, the patient typically has prescription insurance coverage through his or her health plan. In this case, Acument had the health plan that covered its Patient. The health plan contracted with Medco/Express Scripts to supply prescription drugs, including specialty drugs like Acthar. Express Scripts thus collects payments for the price of Acthar from the payer on behalf of Mallinckrodt. Later, Acument's health plan contracted with CVS Caremark to provide prescription drug services for its covered employees and their families. CVS Caremark, like Express Scripts, thus collects payments for the price of Acthar from the payer on behalf of both Express Scripts and Mallinckrodt, and transfers a portion of those payments to the Defendants.

105. By these arrangements, Acthar product flows directly from Mallinckrodt through Express Scripts to the patient, while the money flows directly from the patient and payor through Express Scripts back to Mallinckrodt for all payers who contract with Express Scripts for PBM services. For payers who contract with other PBMs, like Acument in 2015 and 2016, the money flows indirectly through the other PBM and then on to the Defendants. However, the product flow remains direct, as depicted in Figure 1 above.

106. Wielding both the largest collection of patients in the United States and a direct shipment channel for specialty drugs, Express Scripts is in a unique position to negotiate the most competitive, discount prices for specialty drugs in the United States. This bargaining power has allowed Express Scripts to push back against attempts by pharmaceutical drug manufacturers to charges inflated prices for drugs above the actual market value of the drugs.

107. Mallinckrodt leveraged and enhanced its monopoly power by limiting the distribution of its sole specialty drug to just one specialty pharmacy distributor, CuraScript, and employing as its agents, Express Scripts, Accredo and UBC, along with CuraScript, to coordinate all aspects of the distribution and sales of Acthar: from prescription by the physician, to direct home delivery to the patient, to direct reimbursement by the payor. This allowed Mallinckrodt to raise its prices tenfold initially, and nearly double in the ensuing years.

Express Scripts Lowers the Cost of Daraprim

108. Turing Pharmaceuticals, LLC ("Turing") acquired the rights to Daraprim, and proceeded to increase the price 5000% from $13.50 to $750.00 per pill. One year's course of treatment rose from $6,500 to $361,000.

109. Strikingly, Express Scripts employed its market power to counter Turing's action. It worked to create an alternative that was much less expensive than Daraprim.

110. On December 1, 2015, Express Scripts announced that it would "partner with Imprimis Pharmaceuticals to drive access to a low-cost alternative to Daraprim." "Express Scripts Champions $1 per Pill Access to an Alternative for Daraprim", Dec. 1 2015, http://lab.express-scripts.com/lab/insights/drug-options/express-scripts-champions-1-per-pill-access-to-an-alternative-for-daraprim. In partnership with Express Scripts, "Imprimis [] offer[ed] a compounded oral formulation of pyrimethamine and leucovorin (a form of folic acid) for as low as $1 per capsule for people whose pharmacy benefit is managed by Express Scripts." Id. When it is in Express Scripts' interest, it acts to "improve access and affordability." Id.

111. Express Scripts' Chief Medical Officer, Dr. Steve Miller, stated that Express Scripts had found a way to deliver "a safe, high-quality and extremely cost-effective way to provide access to a Daraprim alternative." However, because of its agreement with

Mallinckrodt, Express Scripts has not served as an effective agent for pharmaceutical buyers to seek to lower the cost of Acthar, or the availability of reasonably priced alternatives.

Acthar Pricing Manipulation

112. Mallinckrodt acquired the rights to Acthar from Aventis in July 2001.

113. At the time of its acquisition, the end payor price of a vial of Acthar was approximately $40.00.

114. After acquisition, Mallinckrodt raised the per vial substantially. By September 2001, Mallinckrodt raised the list price for Acthar, or the wholesale acquisition cost ("WAC"), to $748.16. It raised the end payor price, or the average wholesale price ("AWP"), to $935.20.

115. From 2001 until Mallinckrodt executed its new strategy in 2007, the WAC grew from $748.16 to $1,650.23, while the AWP grew from $935.20 to $2,062.79.

116. The below table reflects the WAC price changes implemented by Mallinckrodt from 2001 through February 2007:

Sept. 21, 2001	$748.16
June 24, 2002	$782.60
April 1, 2003	$859.20
March 1, 2004	$902.00
January 1, 2005	$988.00
April 1, 2005	$1,037.20
January 1, 2006	$1,120.40
October, 1, 2006	$1,232.44
December 21, 2006	$1,269.41
February 2, 2007	$1,650.23

117. When Mallinckrodt implemented its new strategy on August 27, 2007, it raised the WAC for Acthar from $1,650.23 to $23,269.00. It also raised the AWP for Acthar from $2,062.79 to a staggering $29,086.25 – representing a 1,310% increase in the span of a month, and a 72,615% increase from the time Mallinckrodt first acquired the drug.

118. Express Scripts was keenly aware of this price increase, as it participated directly in the decision-making with Mallinckrodt. However, when it reported the increase to its customers and the public as part of its annual "Drug Trend Report" for 2007, Express Scripts reported only that Acthar "experienced a significant price increase in 2007."[8] It further stated that "[i]n August 2007, the manufacturer of this drug increased its wholesale price from $2,062 per vial to more than $29,000 per vial, increasing the average cost per prescription to $11,041."

119. This statement by Express Scripts was false, misleading and deceptive. It sought to lay the blame for the price increase on the manufacturer of Acthar, Questcor, without revealing the truth about its direct involvement in decision to raise prices in the wake of contracting for exclusive distribution rights.

120. Until Mallinckrodt obtained FDA approval for the IS indication in 2010, the price of Acthar remained relatively stable. However, in 2011, Mallinckrodt increased the price of Acthar three times: by 5% on January 3, 2011, by another 5% on June 1, 2011, and then by 6.5% on December 27, 2011. These three price increases totaled a staggering 16.5% in one year. As of 2012, Acthar's end payor price/AWP stood at $34,150.00.

121. Each such price increase was reviewed with Express Scripts and approved by Express Scripts, in writing, as required by the parties' written agreements.

[8] Express Scripts 2007 Drug Trend Report at p. 35, available at http://lab.express-scripts.com/lab/publications ("2007 Drug Trend Report").

122. Despite the fact that both Mallinckrodt and Express Scripts were keenly aware that Acthar pricing was a sensitive topic for payors, like Acument, they continued to the raise the Acthar prices each year. They raised the price by 5% on May 15, 2012.

123. Further, as discussed more fully below, Mallinckrodt, along with Express Scripts, continued to conceal and suppress the truth about their coordinated conduct in raising Acthar prices, and continued to misrepresent publicly the reasons for the many Acthar price increases.

124. A poignant example is the attempted price increase in September of 2012.

125. That month, Mallinckrodt desired to take another 5% price increase. The decision to raise the Acthar price was made by Questcor's COO Steve Cartt in early September. Mr. Cartt then communicated with Express Scripts executives via email on September 5 to seek their approval, as required by the parties' agreements. Their intention was to make the price increase effective on September 25, 2012.

126. There was no expectation by either Mallinckrodt or Express Scripts that the additional 2012 price increase – raising the total increase for the year to 10% – would materially impact Acthar ordering levels, due to the monopoly Mallinckrodt held over Acthar and the substantial assistance of the Express Scripts Entities in ensuring that Acthar was prescribed, and paid for, at the ever-increasing price levels.

127. Furthermore, the parties jointly agreed to conceal their joint agreement, keeping their awareness of and involvement in the price increase on a "need to know" basis within their respective organizations.

128. However, before the parties' could finalize their agreement to raise the Acthar price by an additional 5% for 2012, a problem arose. On September 19, 2012, health insurer Aetna announced that it would cut back reimbursements for Acthar, due to the lack of evidence

of Acthar efficacy for various disease states among other reasons.

129. Questcor's stock (as opposed to Mallinckrodt at the time) declined 56% the same day as the Aetna announcement. Within a week, Questcor's stock fell another 37%.

130. Mallinckrodt and Express Scripts then jointly agreed to place the intended price increase on hold, due to the Aetna situation.

131. This price increase was later taken by Mallinckrodt and Express Scripts on June 7, 2013, when the Acthar WAC was increased 5% to $30,120.00 and the Acthar AWP was increased 5% to $37,650.

132. In 2014, Mallinckrodt and Express Scripts resumed their aggressive price increase strategy, just prior to Mallinckrodt plc's $5.9 billion acquisition of Questcor.

133. On January 16, 2014, the Acthar WAC and AWP were raised 5%, to $31,626 and $39,532.50, respectively.

134. Prior to Questcor's acquisition by Mallinckrodt plc in 2014, Questcor had planned an additional 5% increase for Acthar in December 2014. This would have meant a total percentage increase of 10% for the year.

135. However, after the acquisition, Mallinckrodt raised the planned increase to 8.9%, or 13.5% for the year.

136. On December 14, 2014, Mallinckrodt notified Express Scripts of the impending 8.9% price increase.

137. In the interim, the Executive Committee ("EC") of Mallinckrodt met. The EC consists of the senior management of Mallinckrodt, including President and CEO Mark Trudeau and Executive Vice President and Chief Commercial Officer Hugh O'Neill.

138. COO O'Neill raised the matter of the 8.9% price increase with the EC on Friday

December 12, 2014, and it was decided by the Mallinckrodt leadership team to "change[] the magnitude" of the pricing action, reducing the proposed increase from 8.9% to 2%. The EC did this in order to take advantage of a future "opportunity for breakthrough pricing strategies" in the future.

139. It is believed and therefore averred that such pricing opportunity was presented by the Synacthen acquisition.

140. As described more fully below, under the section titled the "Mallinckrodt Synacthen Acquisition", Mallinckrodt completed its acquisition of Synacthen in 2013.

141. As a result of such Synacthen acquisition, and the existing express agreements and implied understandings with the Express Scripts Entities that Synacthen would not be brought to market to threaten the established Acthar monopoly prices, Mallinckrodt was confident that reducing the planned 8.9% Acthar price increase in late 2014 to little more than the consumer price index [which stood at about 1.7% in 2014] -- causing a $26 million shortfall in the forecasted revenues [based on the 5% increase that was "baked in" for December] -- would not negatively affect the company moving forward. This decision, while ostensibly made against Mallinckrodt's economic self-interest, was made to further enhance the monopoly profits of all Defendants in the long run.

142. Accordingly, with the direct input and hands-on decision-making by President and CEO Trudeau, Mallinckrodt reduced its December 2014 Acthar price increase to 2%. This led to a WAC increase to $32,260.00 and an AWP increase to $40,325.00, respectively, on December 16, 2014.

143. Due to its already announced intention to effectuate an 8.9% price increase, Mallinckrodt had to correct its prior notice to Express Scripts. However, Express Scripts agreed

with both decisions, even though the lower price increase was far better for Express Scripts' direct customers and indirect purchasers, like Acument, than the announced 8.9% price increase.

144. Mallinckrodt then notified the other Express Scripts Entities, as well as the pricing compendia that published its AWP for Acthar, of the new price increase.

145. Under Mallinckrodt plc's stewardship, the AWP of Acthar continued to rise in to well above $40,000, while Acument was paying for it.

146. Remarkably, Mallinckrodt's CEO, Mark Trudeau, deliberately lied to the public in a press release, directly responding to Rockford's and Acument's claims against the Defendants. He willfully misrepresented that "[t]he current 'list price' per vial for the drug is $36,382, not the higher numbers which have appeared in various reports, and Mallinckrodt discounts this list price to both public and private payers." *See* Mallinckrodt's June 29, 2018 Press Release H.P. Acthar® Gel Value to Patients attached hereto as Exhibit "C".

147. The price paid by "private payers" like Acument is the AWP. As set forth above, that price has been in excess of $40,000 since 2014. Mallinckrodt does not "discount" that price to Acument, or any other private payer, as claimed.

148. If Mr. Trudeau was actually representing that the WAC for Acthar was $36,382 as of June 2018, which is not the end payer price paid by private payers like Acument, then the AWP paid by private payers was actually a staggering $45,477.50, based on the historical 25% markup Mallinckrodt has employed for its Acthar AWPs!

149. Since the acquisition of Acthar in 2001, the end payor price of Acthar has grown a over 100,000% reflecting the precipitous rise in the value of the Acthar assets from $100,000 in 2001 to $5.9 billion in 2014 – a 5,899,900% increase in value. The dramatic increase in value of the Acthar assets, coupled with the durable and repeated ability to raise the price of Acthar,

underscore the monopoly power wielded by Mallinckrodt in the ACTH market. Mallinckrodt's tactics described in this Complaint, however, reflect Mallinckrodt's willingness to undertake actions to maintain and grow its monopoly in the ACTH market, in violation of the antitrust laws.

150. Mallinckrodt has continued to deceive payors like Acument and the public about the actual prices of Acthar, and the reasons for its many price increases.

151. In fact, in direct response a lawsuit filed against Mallinckrodt in April 2017, Mallinckrodt issued a public statement, claiming to "set the record straight" about Acthar pricing and other issues. *See* Mallinckrodt's June 29, 2018 Press Release H.P. Acthar® Gel Value to Patients attached hereto as Exhibit "C". This Press Release is replete with misrepresentations and deliberate falsehoods that only continues to try deceive the public about Acthar pricing and reasons for the high Acthar prices.

152. Defendants named herein all conspired and agreed to conduct a fraudulent scheme and conspiracy to deliberately inflate the AWPs for Acthar and to maintain such high AWPs for Acthar in the face of complaints by patients and payors, like Acument. As Defendants well know, the AWP is used by government and private assistance programs for prescription drug reimbursement.

153. Government and private assistance programs have used the AWPs published in pharmaceutical industry publications, such as the Red Book and Medispan, for years as a basis for reimbursement, in whole or in part.

154. These publications set forth the AWP for Acthar. However, in periodically announcing the AWPs for Acthar, the publications simply published the prices that were supplied to them by the Mallinckrodt, as agreed to by Express Scripts. These Defendants knew

that they could, and did directly, control and raise the AWP for Acthar at any time simply by forwarding to the pricing compendia a new and higher AWP.

155. This scheme allowed the Defendants to control, as part of their sales, marketing and distribution strategies, their respective profit levels by the direct manipulation of the Acthar AWP.

156. Years before Defendants engaged in their scheme to increase their monopoly profits, in 2003, the Office of Inspector General ("OIG") admonished, "[i]f a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated." *In re Pharm. Ind. Average Wholesale Price Litig*., 491 F.Supp. 2d 20, 39-44 (D. Mass. 2007). Ironically, this published decision appeared the same month that Mallinckrodt and Express Scripts signed their first of many conspiratorial agreements to manipulate the AWP for Acthar.

157. Thus, as of 2003, the OIG had made it clear to prescription drug manufacturers, like Questcor, that the deliberate manipulation of AWP put the company at potential risk under the federal anti-kickback statute. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 FR 23731-01 (May 5, 2003).

The Views of Express Scripts' Chief Medical Officer,
Dr. Steve Miller, on Express Scripts' Market Power

158. Beginning in 2007, Express Scripts became the exclusive agent of Mallinckrodt for the distribution of Acthar. When Mallinckrodt chose to increase the price of this 50-plus year old medication, Express Scripts did not push back. Instead, when confronted with the 2007 price increase, Express Scripts' Chief Medical Officer Steve Miller stated that "[t]he increase was a

manufacturing decision. I can't comment on it."[9]

159. The circumstances of this case demonstrate why Dr. Miller chose to stay silent in the face of Express Scripts' decision to join Mallinckrodt in overcharging payors for Acthar.

160. Express Scripts' Director of Network Audit in Supply Chain, Greg Blaies, has stated under oath that "Express Scripts' mission is to make prescription drugs safer and more affordable for its clients and their members. Express Scripts provides value to its client health plans by reducing waste and inefficiency in prescription drug spend."

161. However, in the case of Acthar, Express Scripts did the opposite: it conspired and agreed with the manufacturer of Acthar to raise the prices of Acthar, to the substantial detriment of its clients, and other third party payors, like Acument, who pay for the Acthar supplied by Express Scripts directly to its members.

162. By the time Acument's Patient was prescribed Acthar, Express Scripts was handling each and every aspect of Acthar distribution through the above-described functions. CuraScript was the exclusive specialty pharmaceutical distributor, Accredo was the specialty pharmacy provider, and UBC coordinated both the product and money flows through the ASAP Program. As Mallinckrodt's exclusive agent, Express Scripts had no interest in lowering the price for Acthar because it was making money off all aspects of its exclusive arrangement with the manufacturer. In other words, by helping Mallinckrodt maintain and enhance its monopoly power in the ACTH market, Express Scripts along with Mallinckrodt realized greater profits at the expense of payors, like Acument.

163. On May 19, 2017, just weeks after Mallinckrodt and Express Scripts had been sued by the City of Rockford in early April 2017 for, inter alia, price fixing, Express Scripts senior officers made comments about the "somewhat controversial" drug Acthar on a private

[9] *Freudenheim*, *supra*.

investor conference call hosted by Citi. 10 The Citi interviewer stated, "it's been in the news as – given the pricing around the drug over the past – I don't know – 12 months at least," and then asked for "any thoughts around … how that can be managed and how you see cost of the playing out?" Citi Transcript at 12.

164. In response, Express Scripts' Senior Vice President, Supply Chain and Specialty Pharma, Everett Neville stated:

> I don't think [Acthar is] a very great [drug] – ***it's a pretty poor drug with a very limited need*** and certainly [Express Scripts Chief Medical Officer, Dr,] Steve [Miller] could comment. He's a doctor and I'm just a really bad pharmacist.
>
> …[Y]ou know, and Steve, you could chime in here too, but I think Steve and I both would agree, and ***I think everybody in our company would agree, that the product is vastly overpriced for the value***. ***We don't set the price.*** We've told [Mallinckrodt] that. I personally told [Mallinckrodt's] management team that their drug is hugely overpriced. I know Steve has as well.

Citi Transcript at 12 (emphasis added) (brackets added).

165. Many of these statements were false, misleading and deceptive when made. They were made willfully, in order to deceive the public and payors, like Acument, who were paying the "vastly overpriced", inflated AWPs for Acthar, as set by both Mallinckrodt and Express Scripts under exclusive agreements concealed from the public through confidentiality provisions in the agreements.

166. What was true is that Acthar had a "very limited need". But Express Scripts did nothing to limit the prescription approval (through Accredo), the distribution (through CuraScript), or the coordination of payment (through UBC) for Acthar, because it was making money off the monopoly profits realized by the "vastly overpriced" Acthar sales.

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[10] *See* Conference Call Transcript of call hosted by the Citigroup Healthcare Team on May 19, 2017 at 11:00a.m. est, with Dr. Steve Miller, Chief Medical Officer from Express Scripts, and Mr. Everett Neville, Senior Vice President of Supply Chain and Specialty ("Citi Transcript") at https://ir.citi.com/l2GW3%2FspXqa99R2rvpFJS8QKZpf%2BRi62n5DFshd7bPciqQPr7uiAlekB%2FjbbEhWR

167. Mr. Neville also made deliberate, willful misrepresentations about the roles of CuraScript and UBC in the maintenance of Mallinckrodt's monopoly and price fixing schemes.

168. As for UBC, while he admitted that Express Scripts "interacts" with Acthar through UBC, he claimed that UBC only "does pharma services [like] running the patient assistance program, pre-screening drug program [t]hat is for patients that meet a need-based criteria for poverty." Citi Transcript at 12 (brackets added). Clearly, as set forth above, UBC does much more in its central role as the hub of the Express Scripts/Mallinckrodt relationship and the sole operator of the ASAP.

169. As for CuraScript, while Mr. Neville admitted that Express Scripts "interacts" with Acthar through CuraScript, he sought to deliberately conceal the exclusive distribution arrangement, claiming "[w]e wholesale the drug, i.e., we sell it to physicians, for office use, which is where most of this [Acthar] is used. We don't control the criteria whether the drug is used or not used or paid or what [is] paid. We merely serve the same role that an ABC [AmerisourceBergen] or a Cardinal or McKesson would in supplying a product with a very minimal markup to a physician. That's it." Citi Transcript at 12 (brackets added).

170. Clearly, as set forth above, CuraScript does much more as the exclusive distributor of Acthar for Mallinckrodt, shipping the drug directly to patients, not their doctors, and charging the patients and their third-party payors, not the doctors, for the drug. CuraScript also applies more than a "minimal markup" to Acthar's price charged to third party payors, like Acument.

171. Finally, Mr. Everett sought to willfully deceive the public and consumers of Acthar by stating, "[t]his is a drug that has very little impact in our company." Citi Transcript at 12. In conspiring and agreeing with Mallinckrodt to raise and fix the AWP-based prices of

Acthar to exorbitant, anticompetitive levels, and in conspiring and agreeing with Mallinckrodt to keep Synacthen off the market to maintain and enhance Mallinckrodt's monopoly, Express Scripts worked to protect its share of the Acthar monopoly profits, the loss of which would have had a huge "impact" on the Express Scripts Entities.

172. On the same conference call, Dr. Miller stated that he was in "100% agreement with [Mr.](Everett)." Citi Transcript at 12 (brackets added). Then, he added, "[i]f you look at the data, the indications for the drug are really – while it had, in the compendium, it's listed under a lot of indications, its real use should be very, very limited. It's an old drug. There's better products in the marketplace and so we're going to continue to be very vigilant in our utilization management." Citi Transcript at 12-13.

173. Despite this express acknowledgment by Express Scripts' Chief Medical Officer, in the weeks and months following Mallinckrodt's settlement with the FTC, Express Scripts did not act to contain costs, to limit prescriptions of Acthar where it has not be shown to be effective, or to provide a reasonable alternative for Acthar, such as the Synacthen Depot owned by Mallinckrodt.

174. Indeed, it was not until December 21, 2017 that Express Scripts provided an updated "Prior Authorization Policy" for Acthar, effective January 2018 (hereinafter "2018 Prior Authorization Policy") – far too late to save payors like Acument from the exorbitant overcharges it suffered in 2015 and 2016 as a result of the conspiracy between Mallinckrodt and Express Scripts, with the substantial assistance of Dr. Tumlin.

175. As discussed more fully below, Dr. Tumlin prescribed the Acthar to Acument's Patient for the treatment of nephrotic syndrome, specifically idiopathic membranous nephropathy (iMN), and also produced the "limited data" on the use of Acthar for such treatment

which Express Scripts' senior management now was rejecting. See 2018 Prior Authorization Policy at 6 ("very limited data have studied the use of Acthar, in patients with diagnoses including idiopathic membranous nephrology (iMN)…", citing articles published by Dr. Tumlin).

176. It is believed and therefore averred in his role as Express Scripts' Chief Medical Officer, Dr. Miller reviewed and approved of the updated 2018 Prior Authorization Policy.

177. In that update, Express Scripts finally, affirmatively admitted all the following facts about Acthar, in particular that it should not have been "recommended for approval" by Dr. Tumlin for treatment of iMN in Acument's Patient for more than a year:

a. "Initial approval of Acthar in the US was in 1952. At that time, original **approval only required** that the medication was safe for human use." 2018 Prior Authorization Policy at 4 (emphasis supplied)

b. "Other reviews have been published regarding nephrotic syndrome but do not mention use of Acthar or note that experience with the agent is **far too preliminary**." *Id*. (emphasis supplied)

c. "The recommended authorization criteria address the use of Acthar in infantile spasms and MS exacerbations in adults. Regarding Acthar's other uses [like nephrotic syndrome and iMN], **data and guidelines do not suggest** that Acthar has a substantial role in therapy. Further data are needed before use in other areas can be recommended." *Id*. (emphasis supplied)(brackets added).

d. In its "Policy Statement", Express Scripts stated, "[p]rior authorization is recommended for prescription benefit coverage of Acthar. The recommended authorization criteria address the use of Acthar in infantile spasms and MS exacerbations in adults." But even as to these limited indications, "[a]ll approvals are provided for one month in duration, where 1 month is equal to 30 days, unless otherwise noted below." *Id*. at 5.

e. Under a heading titled, **"Conditions Not Recommended for Approval"**, Express Scripts expressly listed **"Treatment of Nephrotic Syndrome"**. *Id*. at 6. That section further explained as follows:

   The prescribing information for Acthar states that it may be used in an edematous state, such as to induce a diuresis or a remission of proteinuria in

> the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. (citing the January 2015 H.P. Acthar Gel prescribing information as its source). However, **very limited data in nephrotic syndrome have studied the use of Acthar, in patients with diagnoses including idiopathic membranous nephropathy (iMN)**, membranoproliferative glomerulonephritis (MPGN), focal segmental glomerulosclerosis (FSGS), minimal change disease (MCD), immunoglobulin A (IgA) nephropathy, class V SLE glomerulonephritis, and monoclonal diffuse proliferative glomerulonephritis. **Other data in nephrotic syndrome are available regarding use of a synthetic ACTH analog that is available in Europe (tetracosactide [Synacthen Depot])**. *Id*. at 6 (emphasis supplied)(brackets in original).

178. Express Scripts expressly took issue with Dr. Tumlin's published data about the use of Acthar for the treatment of nephrotic syndrome in articles published in 201111 (when Dr. Tumlin started Acument's Patient on Acthar) and 2013.12 This is the same data that Mallinckrodt provided to its sales representatives to promote the use of Acthar for the treatment of nephrotic syndrome.

179. It is significant that Express Scripts only made these factual admissions about the lack of efficacy of Acthar to treat nephrotic syndrome after it lost the exclusive distribution rights to Acthar in late 2017, after it was sued by the City of Rockford and Acument.

180. Dr. Miller, Express Scripts Chief Medical Officer, has articulated the power of Express Scripts in the prescription drug marketplace to extract lower prices for its customers, using its tremendous buying power and influence. He has made all of the following public comments:

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[11] Tumlin J, Galphin CM, Rovin BH. Advanced diabetic nephropathy with nephrotic range proteinuria: a pilot study of the long-term efficacy of subcutaneous ACTH gel on proteinuria, progression of CKD, urinary levels of VEGF and MCP-1. *J Diabetes Res*. 2013; 2013:489869 ("Tumlin 2013 Pilot Study").

[12] Bomback AS, Tumlin JA, Baranaski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. *Drug Des Devel Ther*. 2011; 5:147-153 ("Tumlin 2011 Study").

"When I joined the company, we represented 12 million members. We're at 85 million today. That gives us extraordinary sway in the marketplace. If you think about any other aspect of health care, no one else has that many lives that they can represent."[13]

"We have tremendous scale, which allows us to get the best deals for our plan sponsors from both the pharmaceutical manufacturers and also the pharmacies. If any pharmacy chain ever becomes too large, we're able to move our patients and … get the lowest cost."[14]

"I think that because of the continued escalation of cost, you need a PBM now more than ever. And what a best-in-class PBM like Express Scripts does really ensure is great health outcomes and more affordable costs."[15]

"Pharma has shown that they feel very emboldened with their pricing power. We're using our clout in the marketplace to really tamp these down for our clients."[16]

"There are pharma companies that recognize this is in their best interest," he says. "They, like us, want to get to a sustainable marketplace. They know if they're overcharging for drugs that have very little efficacy, that puts them in a competitive disadvantage."[17]

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[13] *Managed Care Magazine Online*, "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma," by Peter Wehrwein, April 2015, https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma

[14] *Business Insurance*, "Q&A: Dr. Steve Miller, Express Scripts Holding Co.," by Shelby Livingston, May 22, 2016, http://www.businessinsurance.com/article/00010101/STORY/305229991/Q&A-Dr-Steve-Miller,-Express-Scripts-Holding-Co

[15] *Managed Care Magazine Online*, "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma," by Peter Wehrwein, April 2015, https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma

[16] *Nightly Business Report*, "Express Scripts Looks to Limit Drug Price Increases," by Meg Tirrell, October 2, 2015, http://nbr.com/2015/10/07/express-scripts-looks-to-limit-drug-price-increases/

[17] *Medical Marketing and Media*, "Express Scripts' Steve Miller Takes on Drug Industry in Pricing Battle," by Jaimy Lee, February 1, 2015, http://www.mmm-online.com/payersmanaged-markets/express-scripts-steve-miller-takes-on-drug-industry-in-pricing-battle/article/460559/

> "Discussions to control costs have never been more important, as recent estimates put global drug spend at $1.5 trillion by 2021, according to data from Quintiles IMS Holding. Yet sometimes, in the drug pricing debate, blame is placed on one part of the drug distribution system when, in fact, all of us – pharmaceutical companies, pharmacy benefit managers (PBMs), policymakers and payers – have a role to play in achieving better affordability and accessibility for medicine. As the largest PBM, our job is to make sure our patients, and our clients who provide them a pharmacy benefit, are getting medicines at the lowest net cost while working with our industry partners to make that possible."[18]

> "…[I]t is incumbent upon the pharmacy benefits managers to more forcefully illustrate the critical role we play in making medicine more affordable and accessible. For example, we partnered with a drug maker who was willing to lower the price of its hepatitis C drug. In doing so, we were able to provide 50,000 patients affordable access to this medication."[19]

> "The biggest problem is not new expensive drugs but repricing old ones, and not just ones being purchased by Martin Shkreli or Valeant. 'You have no new research. You have no innovation. You have nothing but increased drug prices."[20]

> "We are constantly trying to be vigilant and chase the bad actors out of the marketplace."[21]

181. Through such statements, Express Scripts acknowledged its strong influence on

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[18] *Real Clear Health*, "Is Drug Pricing at an Inflection Point?" by Dr. Steve Miller, April 14, 2017, http://www.realclearhealth.com/articles/2017/04/14/is_drug_pricing_at_an_inflection_point_110550.html

[19] *Real Clear Health*, "Is Drug Pricing at an Inflection Point?" by Dr. Steve Miller, April 14, 2017, http://www.realclearhealth.com/articles/2017/04/14/is_drug_pricing_at_an_inflection_point_110550.html

[20] *Forbes, Pharma & Healthcare*, "Solving Pharma's Shkreli Problem," by Matthew Herper, January 20, 2016, https://www.forbes.com/sites/matthewherper/2016/01/20/solving-pharmas-shkreli-problem/#6dcce78c6be3

[21] The New York Times, "Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out," by Katie Thomas, January 9, 2017, https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html

pharmaceutical markets. The striking feature of the current circumstance is that Express Scripts has not asserted its influence to effectuate lower prices for Acthar.

182. While acknowledging the lack of "value" of the medication does not warrant its high prices, Express Scripts has facilitated, rather than forestalled, Mallinckrodt's desire for ever growing profits by "repricing" an "old drug".

183. Ironically, just one month after Express Scripts was sued by the City of Rockford in April 2017 for antitrust, Dr. Miller appeared on CNBC's program "Squawk Box". On May 31, 2017, Dr. Miller stated, "when there's competition in the marketplace, we [Express Scripts] do a great job of holding down prices. When we have competition in the marketplace, we are able to play them [the drug companies] off against each other." 22

184. On the same program, in direct response to a line of questioning about the increased pricing of Mylan's Epipen, Dr. Miller further stated as to Epipen:

> It's a 100 year-old drug in a 20 year-old pen that used to be $95 for a two-pack. Over the course of several years, they raised the price to $600. So, only one company controls that, that's the manufacturer.
>
> So, what really works is when we [Express Scripts] can move market share, we can bring prices down. You guys saw this in Hepatitis C. When we got competition into the marketplace, the market worked. We brought the price of Hepatitis C down by over 50%. It's actually cheaper in the United States then it is in Europe. So, that's when the market really is working.

185. The situation described by Dr. Miller about Epipen is similar to Acthar in that one drug manufacturer "controlled" the product. However, with Acthar, unlike Epipen, the manufacturer went to the largest payor representative, Express Scripts, conspired and agreed to preclude competition in the marketplace, to maintain and enhance monopoly power and to continue to fix and raise prices without issue.

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[22] https://www.cnbc.com/video/2017/05/31/competition-is-key-to-contain-drug-prices-dr-steve-miller.html?hootPostID=a33432e4e0f1a67ae2bd68ae4bdf65d6

186. In an article published by Forbes Magazine on February 8, 2016, titled "Solving Pharma's Shkreli Problem", Dr. Miller was presented with the problem of "repricing" old drugs, like Acthar and "the ones being purchased by Martin Shkreli or Valeant", including Turing's Daraprim. He responded, "[y]ou have no research. You have no innovation. You have nothing but increased drug prices." What Dr. Miller failed to acknowledge publicly is that the increased prices of Acthar we caused due in large part to Express Scripts' decision to withhold its market power to effectuate lower prices for Acthar by its exclusive agreements with Mallinckrodt to set the prices of Acthar at anticompetitive levels.

THE MALLINCKRODT SYNACTHEN ACQUISITION AND EXPRESS SCRIPTS' ROLE IN THE MAINTENANCE OF MONOPOLY PRICING FOR ACTHAR

187. Since 2007, Acthar has provided the vast majority of Mallinckrodt's revenue. Acthar was so important to Questcor that its then-CEO, Don Bailey announced publicly on multiple occasions that Questcor "is basically a single product company."23

188. Through its exorbitant price increases, Mallinckrodt was able to grow its revenue from Acthar sales from less than $1 million in 2001 to $798.9 million in 2013. Much of this increase occurred between 2011 and 2013 when Mallinckrodt's revenues increased $218.2 million to $798.9 million.

189. However, by 2013, Mallinckrodt had identified a competitive threat. Novartis AG ("Novartis") had developed Synacthen Depot (cosyntropin depot) ("Synacthen"), a synthetically derived ACTH medication, which, like Acthar, could be injected intra-muscularly. While it was used outside the United States, it was not yet approved by the FDA for use in the United States.

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[23] Exhibit 99.1 to Questcor form 8-K, Aug. 11, 2011 Canaccord Genuity Conference Transcript at 1; *see also* UBS Investment Bank's Global Life Sciences Conference, Sept. 19, 2011, Transcript at 2 (wherein CEO Bailey stated "Questcor is a single-product company" and affirmed "this presentation was filed with the SEC on [September] 9th").

Recognizing that the entry of Synacthen in the U.S. market for ACTH drugs would threaten its exercise of its monopoly power, Mallinckrodt first attempted to buy the rights to Synacthen in 2009. It failed.

190. As of 2013, Novartis agreed to sell Synacthen to Retrophin, Inc., which at the time was helmed by Mr. Shkreli. Mr. Shkreli founded Turing (the maker of Daraprim) after he departed Retrophin.

191. When faced with a competitive threat to its monopoly, Mallinckrodt disrupted the bidding process for Synacthen by intervening at the last minute to pay multiple times what had been offered by three competitors, including Retrophin. Retrophin had agreed to buy Synacthen for $16 million. Upon learning of this imminent threat, Mallinckrodt acted to protect and enhance its monopoly power by licensing Synacthen for a minimum of $135 million from Novartis. It licensed the U.S. exclusive rights to Synacthen from Novartis, not to bring this viable synthetic alternative to Acthar to market, but to eliminate the nascent competitive threat posed by an independently owned Synacthen.

192. Acquiring Synacthen allowed Mallinckrodt to maintain and enhance its monopoly power in the ACTH market by removing a competitive threat from the marketplace. The Synacthen acquisition had the purpose and effect of suppressing competition and allowing Mallinckrodt to continue to raise prices for Acthar, which it did.

193. From 2013 through 2017, Mallinckrodt raised the price of Acthar from $36,144 to $43,658.

194. But Mallinckrodt could not have gotten away with increasing its monopolistic prices without the express written consent of Express Scripts, as required by the parties' contracts. Accordingly, Express Scripts had to agree with Mallinckrodt to allow it to not bring

Synacthen to market.

195. While the details of this consent are not yet known, and can only be discovered by Plaintiff through discovery in this case, this much is known.

196. As the largest PBM in America, and the exclusive distributor of Acthar for Mallinckrodt, Express Scripts knew that Mallinckrodt had acquired Synacthen Depot from Novartis. It is believed and therefore averred that Express Scripts also knew at the time of the Synacthen acquisition that there were other bidders for Synacthen, who were expecting to bring the product to market to directly compete with Acthar.

197. Certainly, after Retrophin sued Mallinckrodt in January 2014, which lawsuit is discussed below, these facts were known to Express Scripts. And yet, Express Scripts did nothing to force Mallinckrodt to bring Synacthen to market to compete with Acthar to lower Acthar prices for the benefit of its direct-purchasing customers, like Rockford, and indirect purchasing customers, like Acument.

198. Instead, Express Scripts continued its unlawful conspiracy and agreements with Mallinckrodt to maintain inflated monopoly prices for Acthar, unchallenged by Synacthen competition.

199. In its 2018 Prior Authorization Policy, Express Scripts acknowledged that "[o]ther data in nephrotic syndrome are available regarding use of a synthetic ACTH analog that is available in Europe (tetracosactide [Synacthen Depot]). Id. at 6. And yet, Express Scripts did not utilize its substantial market power for force the competition that its Chief Medical Officer Dr. Miller affirmed is critical to lowering drug prices, as it did in the case of Daraprim discussed above.

THE QUI TAM WHISTLEBLOWER COMPLAINT AGAINST MALLINCKRODT

200. On April 30, 2019, CNN reported that the United States Department of Justice ("DOJ") had intervened in a false claims act action brought by two former employees of Mallinckrodt.

201. The intervention actually took place the month before, on March 6, 2019, but the case was sealed at the time. *See Plaintiff Under Seal v. Defendant Under Seal*, Civil Action No. 12-CV-0175-BMS, E.D.Pa., at Dkt. No. 55. The government's decision to intervene, a relatively rare occurrence, was done after the government conducted its own extensive investigation of the claims by the former employees and concluded that the allegations are credible.

202. The case, now known as U.S. ex. Rel. Charles Strunck and Lisa Pratta, was filed in 2012 by Charles Strunck, New York-based former Multiple Sclerosis ("MS") Sales Specialist for Questcor, and Lisa Pratta, a New Jersey-based Acthar neurology specialist for both Questcor and Mallinckrodt (collectively, the "Relators"). Strunck worked from September 2010 through August 2011, while Pratta worked from September 2010 through June 2017.

203. As reported by CNN, and as averred in their Qui Tam Complaint, the Relators allege that Mallinckrodt has engaged in a long—standing scheme to bribe doctors to prescribes Acthar at the exorbitant, inflated prices detailed herein. They claim there was a "culture" at Mallinckrodt designed to sell Acthar at all costs, from lying to the FDA to offering bribes to doctors.

204. Importantly, Mallinckrodt has not denied the allegations. Instead, Mallinckrodt claims the conduct alleged is a "legacy matter" involving Questcor and its conduct prior to Mallinckrodt's acquisition.

205. However, Relator Pratta, who worked at both Questcor and Mallinckrodt after the

2014 acquisition, has alleged that the conduct continues at Mallinckrodt.

206. In a conference call with investors held May 7, 2019, CEO Mark Trudeau publicly stated that the company has reserved for the settlement of the Relators' case and is actively pursuing settlement which he stated is "likely to resolve sooner than later".

207. The conduct alleged by Relators involved kickbacks to doctors in the form of free Acthar, as well as active concealment by Mallinckrodt of the conduct for years.

208. For this reason, Acument did not know and could not have known about such unlawful conduct until the earliest date of April 30, 2019. As a result, Plaintiff's claims stated herein premised upon the unlawful conduct revealed by the Relators' case are timely.

209. Plaintiff had no way of knowing that Mallinckrodt was paying doctors in Tennessee thousands of dollars to prescribe Acthar to their patients.

210. The kickback scheme involved the promotion of Acthar to treat disease states for which Acthar was not the "gold standard", as in the case of IS, and for treatments that were not covered by the Acthar label.

211. For instance, Acthar is approved to treat acute exacerbations of disease. But the scheme uncovered by Relators involved widespread promotion of Acthar for the long-term treatment of disease.

212. In the case of Acument's beneficiary, they have been prescribed Acthar for years to treat nephrology syndrome. As a result of Mallinckrodt's promotional effort, instead of treating Acument's beneficiary for an acute exacerbation, or flare-up, they have been treated with Acthar as maintenance medication for more than a year. Acument was forced to pay hundreds of thousands of dollars for Acthar.

213. The conduct revealed by the Relators goes to the manner in which Mallinckrodt

was able to convince doctors to prescribe the high-priced Acthar, after the Defendant' conspired and agreed to raise the prices and maintain the prices at artificial levels. The conduct involved systematically promoting and marketing Acthar for unapproved off-label uses, including the nephrology syndrome for which Acument's beneficiary was prescribed Acthar.

214. The scheme involved compensating sales representatives thousands of dollars to promote the sale of Acthar for unapproved uses and doses, to benefit Mallinckrodt and the sales reps. Sales representatives have been paid tens of thousands of dollars for such promotional efforts. As detailed in the Relators' complaint, one sales representative was paid a $124,000 bonus in the second quarter of 2011, including $75,000 for just one month. Others received bonuses of $110,000 and $80,000 in the same period.

215. The compensation of sales reps was directly tied to sales growth, a growth that was possible by expanding the approved uses for Acthar which had a narrow, limited market of patients.

216. Mallinckrodt employed a team of "Medical Science Liaisons", like Sagar Shah, who were directed by Nikki Mutschler to join with sales specialists, like Strunck and Pratta to promote the sale of Acthar for unapproved uses.

217. To hide the fact that the promotional effort was for unapproved, off-label uses, Mallinckrodt referred to such uses as "new indications."

218. The sales of Acthar for these "new indications" became a primary focus for Mallinckrodt, as it strived to grow its revenue to the more than $1 billion in sales it achieves each year for Acthar alone.

219. Mallinckrodt achieved such exponential growth, despite the price increases detailed herein, by providing valuable remunerations to doctors to induce and encourage them to

prescribe Acthar for unapproved uses and doses.

220. As the Relators' Complaint reveals, and as Acument alleges herein, Mallinckrodt engaged in such conduct in violation of the Tennessee laws by providing secret kickbacks to doctors throughout the country, including Tennessee, to get them to prescribe Acthar at exorbitant prices, which Acument has been forced to pay, and continues to pay to this day. As detailed herein, Dr. Tumlin received hundreds of thousands of dollars from Mallinckrodt to prescribe Acthar. That is why Plaintiff seeks declaratory and injunctive relief against Mallinckrodt to end such practices.

RELEVANT MARKETS, MONOPOLY POWER, AND THE FTC COMPLAINT AGAINST MALLINCKRODT

221. The supra-competitive and exorbitant prices that Mallinckrodt and Express Scripts charge for Acthar, and Mallinckrodt's limitation on distribution through the entry into an exclusive distribution arrangement with Express Scripts in 2007, are direct evidence of Mallinckrodt's monopoly power and actions to maintain and enhance such monopoly power, in violation of the antitrust laws. That Acthar holds a dominant share of the relevant market for ACTH drugs in the United States shows Mallinckrodt's monopoly power by indirect evidence.

222. The exercise of such monopoly power is also shown by Mallinckrodt's acquisition of Synacthen, and decision, without pressure from Express Scripts, to keep Synacthen off the market to maintain and enhance its monopoly prices for Acthar.

223. The relevant product market is the sale of ACTH drugs, dominated by just one product, Acthar. The geographic market for purposes of this case is the State of Tennessee, as part of the larger United States market, but governed by the antitrust laws of this State. In this market, Mallinckrodt is the single seller, and the third party payors are the leading buyers.

224. That market is and has been characterized by significant barriers to entry.

225. There are no medical or reasonably available substitutes for Acthar. The only potential substitute was Synacthen, which Mallinckrodt purchased the rights to from Novartis in 2013, only to shelve the product, with the consent of Express Scripts, rather than seek to bring it to market in the United States, and specifically to the Tennessee market.

226. On January 18, 2017, the Federal Trade Commission ("FTC") sued Mallinckrodt, alleging that Mallinckrodt exercised, and continues to exercise, monopoly power in the United States in the sale of Acthar. See generally, Complaint for Injunctive Relief and Other Equitable Relief ("FTC Complaint") at Exhibit "D" hereto.

227. The FTC alleged that such purchases "extinguished a nascent competitive threat to [Mallinckrodt's] monopoly." FTC Complaint, ¶ 1.

228. At all relevant times material to this case, Mallinckrodt possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales—in the relevant product market. None of the vast price increases taken by Mallinckrodt between 2007 and the present have caused a significant loss of sales. To the contrary, Mallinckrodt's sales have increased during that time.

229. Mallinckrodt has repeatedly and profitably raised Acthar's price from the time it acquired the product for $100,000 in 2001 from Aventis to the present. Mallinckrodt has been able to raise prices unchecked, as set forth above, and achieve corresponding revenue growth to more than $1 billion.

230. Mallinckrodt has encountered no competitive constraints on its ability to repeatedly increase Acthar's price and, by extension, its revenue and profit margins. Mallinckrodt does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly

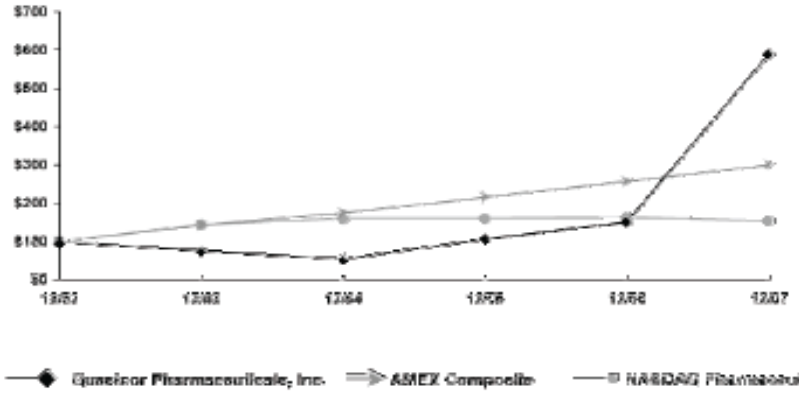
higher than non-ACTH drugs used to treat the same indications, except for IS.

231. Indeed, one Mallinckrodt executive, Steve Cartt, commented that the price for Acthar "was chosen by looking at the prices of other specialty drugs and estimating how much insurers and employers would be willing to bear." According to Cartt, Mallinckrodt took "some comfort that the strategy would work, and physicians would continue to use the drug, and payers would continue to pay." In fact, according to Cartt, the "reality was better than expected."

232. In its Annual Report on Form 10-K for the Fiscal Year ended December 31, 2007, Questcor illustrated the effect of its monopolization strategy on its "5 Year Cumulative Total Return", illustrating a 290% return between 2006 and 2007 as follows:

Comparison of 5 Year Cumulative Total Return*
Among Questcor Pharmaceuticals, Inc.,
the Amex Composite Index
and the Nasdaq Pharmaceutical Index

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Questcor Pharmaceuticals, Inc., The AMEX Composite Index
And The NASDAQ Pharmaceutical Index



	Cumulative Total Return*					
	12/02	12/03	12/04	12/05	12/06	12/07
QUESTCOR PHARMACEUTICALS, INC.	100.00	75.51	54.08	106.13	151.02	588.78
AMEX COMPOSITE INDEX	100.00	143.18	175.20	215.26	257.04	299.37
NASDAQ PHARMACEUTICAL INDEX	100.00	144.89	160.46	160.65	163.42	154.46

* $100 invested on 12/31/02 in stock or index-including reinvestment of dividends. Fiscal year ended December 31.

This stock performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

233. FDA approval is required to market pharmaceuticals to U.S. consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for U.S.

consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

234. Acthar has a 100% share of the market for ACTH drugs in Tennessee and throughout the United States. No other ACTH drug is FDA-approved for therapeutic use.

235. The Tennessee ACTH market, like the larger United States ACTH market, is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's former CEO Don Bailey assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

236. Former CEO Don Bailey also claimed that one of the barriers to entry is the Acthar drug formulation. While Acthar is a biologic extraction of porcine pituitaries, Bailey claimed, "[i]t's an undisclosed composition, so that's a trade secret." He also claimed "[t]he manufacturing process is also a trade secret. It's complex, it's unique, and we own all elements of the manufacturing process. …The composition of Acthar that comes out of the manufacturing process is tied to the process, so if you don't know the process you can't figure out what's actually in Acthar."

237. If what the former CEO was saying was that Mallinckrodt enjoyed a natural monopoly, that does not necessarily imply the absence of market constraints. These constraints can come from a new competitive product, like Synacthen, or from a dominant buyer on the

other side of the market, like Express Scripts. Both of these factors are relevant here.

Mallinckrodt Engaged in Anticompetitive Conduct By Acquiring the Only Competitor Drug, Synacthen

238. Synacthen posed a threat to Mallinckrodt's ACTH drug monopoly, so Mallinckrodt intervened at the time when other firms were attempting to acquire the U.S. rights to Synacthen from Novartis. Mallinckrodt submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Mallinckrodt eliminated the possibility that another firm would develop it and compete against Acthar.

239. Synacthen constituted a nascent competitive threat to Mallinckrodt 's ACTH drug monopoly, notwithstanding the uncertainty that Synacthen, a preclinical drug, would be approved by the FDA.

240. For years, Mallinckrodt viewed Synacthen as a significant potential competitive threat to its monopoly.

241. When Mallinckrodt first decided to pursue an "orphan drug" (i.e., high) pricing model for Acthar, it recognized the potential threat Synacthen posed to Acthar's revenue growth.

242. Nevertheless, in 2007, Mallinckrodt adopted and pursued the above-described "new strategy", consolidating Acthar distribution to just one distributor (Curascript) and streamlining its control over sales and distribution through the implementation of ASAP (run by UBC). These functions were consolidated in one significant company, Express Scripts.

243. In 2009, Mallinckrodt approached Novartis about acquiring Synacthen. At that time, Mallinckrodt continued to view Synacthen as a possible future competitor, especially given the increasing prices Mallinckrodt was commanding for Acthar. Unsuccessful in that initial attempt, Mallinckrodt continued to monitor the competitive threat from Synacthen.

244. Then in 2012, Mallinckrodt again concluded that Synacthen posed a more immediate threat to Acthar if Synacthen was approved for sale in the United States.

245. By 2013, Mallinckrodt feared that if another company were to acquire Synacthen and obtain FDA approval, it could undermine its business model.

246. On information and belief, as long as Mallinckrodt believed no other firm was seeking to bring Synacthen to the United States, Mallinckrodt did not make further attempts to acquire it. Indeed, just months before Mallinckrodt began pursuing the acquisition of Synacthen, top Mallinckrodt officials questioned whether Synacthen would provide any affirmative value to Mallinckrodt.

Other Bidders Planned to Use Synacthen to Challenge Acthar's Monopoly

247. Unbeknownst to Mallinckrodt at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug was already approved and sold. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

248. It is alleged that each of the three firms planned to develop Synacthen for IS and to use Synacthen to compete directly with Acthar. With this indication, each firm expected to capture a significant share of the U.S. ACTH market from Mallinckrodt by pricing Synacthen below Acthar's prices. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the U.S. ACTH market.

The Value of the Synacthen Assets

249. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation has been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

250. The asset package being sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

251. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation de novo, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

Mallinckrodt Disrupted the Synacthen Bidding Process

252. It is alleged that, on October of 2012, Mallinckrodt learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis to develop it to compete with Mallinckrodt for the ACTH market. Mallinckrodt immediately reached out to Novartis, signed a confidentiality agreement with Novartis, and submitted a confidential offer for the purchase of Synacthen.

253. Novartis negotiated with the three alternative bidders in parallel with Mallinckrodt. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company exchanged deal terms with Novartis and submitted formal offers. The offers by the three alternative bidders were

comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on U.S. sales of Synacthen.

254. Unlike the three alternative bidders, Mallinckrodt had only incomplete plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis. Retrophin ultimately prevailed in the bidding war with a bid of $16 million.

255. However, on June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Mallinckrodt and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"). By the Agreements, Mallinckrodt gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Mallinckrodt is obligated to pay a minimum of $135 million, and likely will pay $300 million to Novartis for Synacthen.

256. In other words, Mallinckrodt swept in at the eleventh hour to overpay—at least 8 times more than the market had determined—for the only immediate competitive threat to its monopoly for Acthar. Despite paying this amount, they did not seek FDA approval to bring the product to market.

The Lawsuit Between Retrophin and Mallinckrodt for Mallinckrodt's Antitrust Violations

257. In January 2014, Retrophin sued Questcor (n/k/a Mallinckrodt) for antitrust violations in the United States Federal District Court for the Central District of California. *See Retrophin, Inc., v. Questcor Pharmaceuticals, Inc*., CV-14-00026-JLS (C.D.Cal) ("Retrophin Complaint") (attached hereto at Exhibit "E"). (To the extent relevant to Plaintiff's Complaint, the averments of antitrust conduct interposed by Retrophin are incorporated by reference herein).

258. In the Retrophin Complaint, Retrophin claimed,

> "[i]n June of 2013, plaintiff Retrophin was poised to challenge Questcor's monopoly. It had negotiated an agreement to purchase

> from Novartis AG ("Novartis"), the rights to sell in the US a product called Synacthen. ...
>
> Retrophin planned to obtain FDA approval to sell Synacthen in the US and compete head to head against Questcor by dramatically undercutting Questcor's price for Acthar. It had negotiated and was ready to sign an agreement to purchase the US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013. The signing of the agreement was so imminent that a press release had been prepared to announce the deal.
>
> On June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor swept in and acquired the rights to Synacthen. In doing so, it preserved and entrenched its ACTH monopoly in US and eliminated the competitive threat posed by Retrophin's acquisition of Synacthen. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

Retrophin Complaint, ¶¶ 4-6, at Exhibit "E" hereto.

259. The FTC agreed with Retrophin's assessment.

260. The government, in its 2017 FTC complaint, mirrored Retrophin's 2014 allegations that Mallinckrodt engaged in anticompetitive conduct in violation of the antitrust laws.

261. Mallinckrodt chose to settle the Retrophin lawsuit for $15.5 million, slightly less than the $16 million Retrophin bid to purchase Synacthen from Novartis.

Mallinckrodt's Acquisition of Synacthen Harmed Competition

262. Mallinckrodt's strategy to conspire with Express Scripts and continue to protect its monopoly power in the market for ACTH drugs was successful. But for Mallinckrodt's acquisition of Synacthen, one of the three alternative bidders, including Retrophin, would have acquired Synacthen and pursued its plan to develop Synacthen for IS to compete directly with Acthar at a lower price. With the acquisition of Synacthen, Mallinckrodt was able to thwart an imminent threat to its Acthar monopoly and thereby harmed competition. But it was only

because Express Scripts agreed with Mallinckrodt to not bring Synacthen to market that Mallinckrodt's scheme was successful.

263. Mallinckrodt claimed at the time that it acquired Synacthen to develop it for new, non-Acthar indications, but given the similarities between the two drugs, any therapeutic indication that Mallinckrodt was to pursue for Synacthen could easily have been pursued for Acthar.

264. In a public statement released by Mallinckrodt on June 29, 2018, in direct response to the Rockford lawsuit, Mallinckrodt admitted "Mallinckrodt did not pursue commercialization of Synacthen for IS." However, it falsely claimed that the reason for not doing so was because "the barriers to completion were, in our view, virtually impossible to overcome." See June 29, 2018 Press Release, "The Facts About H.P. Acthar Gel" at Exhibit "C" hereto.

265. Fourteen months after Questcor acquired Synacthen, Mallinckrodt acquired Questcor for $5.9 billion. The vast majority of Questcor's value was attributable to Acthar and Synacthen.

266. However, despite its claims about a willingness to bring Synacthen to market, to date, Mallinckrodt has not brought Synacthen to market for any indication. Instead, it keeps Synacthen off the market to protect its monopoly power and high prices for Acthar. Express Scripts continues to allow Mallinckrodt to restrict competition in the market for ACTH products.

Mallinckrodt Settles with the FTC

267. On January 18, 2017, the FTC announced that Questcor and its new parent Mallinckrodt plc agreed to pay $100 million to settle FTC charges that Questcor and Mallinckrodt violated antitrust laws when Questcor acquired the rights to Synacthen from

Novartis in 2013.

268. According to FTC Chairwoman Edith Ramirez, "Questcor took advantage of its monopoly to repeatedly raise the prices of Acthar, from $40 in 2001 (when it acquired the rights to sell Acthar for $100,000) to more than $34,000 per vial today – an 85,000 percent increase."

269. The brunt of these monopoly prices was borne by self-funded payors, like Acument, located throughout the country, whose employees and beneficiaries whom were at the mercy of Mallinckrodt and treated with Acthar.

270. From the time it sought FDA approval for the treatment of IS, Mallinckrodt has raised the price of Acthar to over $45,000.

271. Remarkably, Mallinckrodt continues to deceive payors like Acument and the public about the true prices of Acthar. In its June 29, 2018 Press Release, "The Facts About H.P. Acthar Gel" at Exhibit "C", Mallinckrodt claimed that "[t]he price of H.P. Acthar Gel today is $38,892, before discounts provided to payors." As set forth above, this is demonstrably false and misleading, as Mallinckrodt raised the WAC for Acthar to $31,626.00 on January 16, 2014, 4 ½ years prior, which in turn raised its AWP to $39,532.50 in 2014. Since that time, Mallinckrodt has raised the WAC multiple times, at least once a year, pushing the AWP to over $45,000.00 in 2018.

272. Mallinckrodt claimed that these exorbitant price increases were in response to demand. But its former Chief Executive Officer, Don Bailey, acknowledged in 2009 that "we only have about 800 patients a year. It's a very, very small – tiny – market." Consequently, the limited use of the product did not justify an over 58,000% price increase from acquisition until 2009.

273. Since the Acthar market for the treatment of IS was so limited, Mallinckrodt

sought to expand its use. By 2012, Acthar was prescribed for Medicare recipients 3,387 times. To Medicare alone, this represented a cost of $141,500,000 in 2012.

274. Quantified another way, Dr. William Shaffer, a neurologist in Greeley, Colorado who was the highest prescriber of Acthar in 2012, wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare $4,000,000.

275. Acthar represented 98% or more of Mallinckrodt's sales and revenue from sales since 2007. Its manipulation of the market has resulted in a 266% increase in revenue year-over-year from 2011 to 2013. Total net sales for Mallinckrodt in 2011 were $218.2 million, $509.3 million in 2012, and $798.9 million in 2013. In each of those years, Acthar represented at least 95% of Mallinckrodt's net sales – over $1.45 billion in revenue.

276. In the words of former CEO Don Bailey "Questcor is basically a single-product company." But, by flexing its monopoly power, Mallinckrodt has been able to raise Acthar prices and increase revenue from Acthar in a "tiny market" from less than $1 million for fiscal 2001 to $799 million for fiscal 2013 - a nearly 80,000% increase. It did so in conjunction with Express Scripts.

277. Mallinckrodt's decision to exclusively contract with the agent for its largest customer to provide limited distribution for Acthar removed Express Scripts' competitive pressure in the marketplace to cause Acthar prices to be lower. Instead, by entering into an exclusive arrangement with Express Scripts, Mallinckrodt was able to enhance its monopoly power and to raise its Acthar prices above competitive prices throughout the relevant time period from 2007 through the present.

Dr. Tumlin's Role in the Acthar Scheme as a Leading "KOL" for Mallinckrodt in the Development and Promotion of Acthar for the Treatment of Nephrology Syndrome

278. In order to effectuate their scheme and conspiracy fully, the corporate Defendants

needed some help with the promotion of Acthar to physicians, especially in the medical fields where Acthar was not the preferred course of treatment. Indeed, Acthar was not approved by the FDA for the long-term treatment of most diseases for which Acthar had a narrow indication from its 1952 label. One such field was nephrology.

Mallinckrodt targets nephrology syndrome as a "potential new market" to promote off-label sales of Acthar.

279. As Express Scripts' 2018 Prior Authorization Policy acknowledged, "data and guidelines do not suggest that Acthar has a substantial role in therapy" for nephrotic syndrome, including iMN. Instead, "[f]urther data are needed before use in other areas [beyond IS and MS] can be recommended." Id. at 4 (brackets added).

280. To overcome this lack of data to support to use of Acthar to treat nephrotic syndrome, and to support its marketing effort in nephrology, Mallinckrodt engaged certain nephrologists strategically situated throughout the country. These doctors became known as "Key Opinion Leaders" or "KOLs".

281. Mallinckrodt turned to KOLs initially to determine whether there was a viable potential market for Acthar with nephrologists.

Mallinckrodt engages KOLs for "white coat marketing" of Acthar to nephrology

282. The monopoly profits realized by the implementation of the "new strategy" in 2007 made it possible for Mallinckrodt to pay doctors to serve as KOLs as part of the Mallinckrodt white coat marketing strategy into nephrology.

283. The practice of "white coat marketing" was identified by the Office of Inspector General (OIG) of the federal government as a potential area of fraud and abuse as early as 1991. See, e.g., OIG Advisory Opinion No. 11-08, issued June 12, 2011, at 6 (citing 56 Fed. Reg. 35952, 35974 (July 29, 1991)). As described in Advisory Opinion No. 11-08:

> The fraud and abuse risks are compounded where, as here, a physician or other health care professional is involved in the marketing activity – a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services – especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35952, 35974 (July 29, 1991). Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch.

284. In order to cultivate KOLs for its white coat marketing scheme, Mallinckrodt directed its sales force call on select nephrologists to discuss their treatment of nephrotic syndrome and to begin sharing the available data on synthetic ACTH treatment.

285. However, it is believed and therefore averred that the only available data was data relating to the use Synacthen Depot in Europe.

286. Mallinckrodt then began working with KOLs, like Dr. Tumlin, were interested in generating new data in the United States to support the off-label use of Acthar to treat nephrology syndrome. This became a major focus for Mallinckrodt in 2009.

Dr. Tumlin is hired as a Mallinckrodt KOL

287. By at least March 2009, Dr. James Tumlin was hired by Mallinckrodt to develop supporting data using his existing patients as test subjects in a non-FDA approved clinical study. Mallinckrodt paid Dr. Tumlin handsomely for such work on behalf of the company.

288. It is believed and therefore averred that around that time Mallinckrodt entered into a contract with Dr. Tumlin to conduct clinical studies of his patients using Acthar to treat their nephrology syndrome. This engagement was not to conduct any FDA-approved clinical study. Instead, it was to pay Dr. Tumlin to conduct clinical studies of his own patients by prescribing Acthar to them for unapproved uses and doses to treat their nephrotic syndrome in order to learn about the effects of Acthar on their disease and assist Mallinckrodt in developing anecdotal data

with which to promote Acthar's use to other nephrologists. One such patient was Acument's Patient.

289. The 2009 contracted study was titled "A Randomized, Placebo-Controlled, Parallel-Group, Double-Blind Study of H.P. Acthar Gel (Acthar) in Treatment-Resistant Subjects With Persistent Proteinuria and Nephrotic Syndrome Due to Idiopathic Membranous Nephropathy (iMN)" (hereinafter, "Tumlin 2009 Randomized Study"). It is believed and therefore averred that Dr. Tumlin "enrolled" 15 patients for this study. While Acument's Patient had iMN, it is unknown to Acument at this time whether its Patient beneficiary was included among the 15 patients Dr. Tumlin treated with Acthar as part of this contracted study. Only discovery will reveal the truth.

290. However, it is known Dr. Tumlin did not charge either the Patient or Acument for the Acthar he prescribed in 2011. Instead, it is believed and therefore averred that Mallinckrodt provided the drug for free in order that Dr. Tumlin could develop data to assist in its marketing and sales of Acthar to other nephrologists. Typically, a prescription drug company will not charge patients for the drug used in a clinical study.

291. Dr. Tumlin's work on behalf of Mallinckrodt became a centerpiece of its marketing plan for nephrologists, not just in Tennessee, where Dr. Tumlin's practice, Southeast Renal Research Institute, was located in Chattanooga, but throughout the country.

292. It is believed and therefore averred that Dr. Tumlin travelled across the country on all expenses paid trips funded by Mallinckrodt to promote the use of Acthar for nephrology syndrome and other disease states for which there were no clinical studies to support the treatment. Instead, it is believed that Dr. Tumlin cited his own anecdotal experience with his patients, about which he published in two papers, the Tumlin 2001 Study and the Tumlin 2013

Pilot Study. See notes 12 and 13 above.

293. While it is not yet known the total dollars Mallinckrodt paid Dr. Tumlin for these two "studies" which led to published articles, it is believed and therefore averred that those monies were only part of Dr. Tumlin's compensation for working for Mallinckrodt.

294. For instance, it is known that Dr. Tumlin conducted a study titled "Safety and Efficacy of Acthar Gel on Albuminuria and Urinary Transforming Growth Factor Excretion in Type II Insulin Requiring Diabetics with Nephrotic Range Proteinuria: A Pilot Study". It is believed that Mallinckrodt paid Dr. Tumlin for that study.

295. In prior authorization update released by Express Scripts in 2018 – 9 years after Mallinckrodt began white coat marketing of Acthar through KOLs like Dr. Tumlin – Express Scripts admitted that Acthar should not have been "recommended for approval" by any doctor, including Dr. Tumlin, for treatment of iMN in patients.

296. In fact, Express Scripts cited Dr. Tumlin's 2 published papers sponsored and paid for by Mallinckrodt, the Tumlin 2011 Study and the Tumlin 2013 Pilot Study,24 in concluding that "very limited data in nephrotic syndrome have studied the use of Acthar, in patients with diagnoses including idiopathic membranous nephropathy (iMN)…". Express Scripts also pointed to the very same European data studying Synacthen's use in nephrotic syndrome as support for its conclusions that Acthar was inappropriate for the treatment of nephrology syndrome.

297. It is significant that Express Scripts only made these factual admissions about the lack of efficacy of Acthar to treat nephrotic syndrome after it lost the exclusive distribution rights to Acthar in late 2017, and after it was sued by the City of Rockford and Acument.

[24] Bomback AS, Tumlin JA, Baranaski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. *Drug Des Devel Ther*. 2011; 5:147-153 ("Tumlin 2011 Study").

298. It is believed and therefore averred that Dr. Tumlin has been paid handsomely for his work on behalf of Mallinckrodt.

299. According to the website sponsored by Propublica,[25] Dr. Tumlin was paid by Mallinckrodt at least the following disclosed sums for his promotional activity selling Acthar to other doctors throughout the country, apart from the monies he has earned conducting clinical studies of his patients:

Aug. 2013 - Dec. 2013	$15,318
Jan. 2014 - Dec. 2014	$27,733
Jan. 2015 – Dec. 2015	$28,839
Jan. 2016 – Dec. 2016	$50,840

300. As described more fully below, Dr. Tumlin began treating Acument's Patient with Acthar to treat iMN in 2011, but did not charge for the drug. He renewed the treatment in December 2015 through December 2016, and this time charged the full, inflated AWP price for the Acthar, as established by Mallinckrodt and Express Scripts.

301. On multiple occasions, Dr. Tumlin was paid twice by Mallinckrodt for the same services and reimbursements.

302. For instance, on May 23, 2016, Propublica reports that Dr. Tumlin received two payments from Mallinckrodt for "promotional speaking" in the amount of $3,400 each. He also received two equal payments of $2,050 for "promotional speaking" July 2, 2015.

303. On June 17, 2015, Mallinckrodt paid Dr. Tumlin the following sums for "travel

[25] *See* https://projects.propublica.org/docdollars/ According to Propublica, "[p]harmaceutical and medical device companies are required by law to release details of their payments to a variety of doctors and U.S. teaching hospitals for promotional talks, research and consulting, among other categories. Use this tool to search for general payments (excluding research and ownership interests) made from August 2013 to December 2016."

and lodging" for just one day: $537, $529, $393, $393, $276, $87, $50, $50, $30, $30 and $22.

304. Based on the Propublica information, it is believed that Dr. Tumlin travelled the country for Mallinckrodt to promote Acthar use in nephrology. Mallinckrodt paid with substantial "honoraria" paid, totaling up to $5,000 at time, for his time and effort.

305. The specific dates, locations and payments relating to these trips lies within the exclusive control of Mallinckrodt and Dr. Tumlin. Only discovery will reveal these details to the Plaintiff.

Acument's Payments for Acthar in Tennessee for Long-Term the Treatment of iMN, and Antitrust Injury

306. Throughout the relevant time period, Acument has provided healthcare benefits to its employees through Blue Cross Blue Shield of Michigan. Since 2010, Acument has provided prescription drug benefits for its employees. At the time, and through 2011 when the Patient was prescribed Acthar, Acument's prescription drug benefits were administered by Express Scripts. When the Patient was prescribed Acthar a second time in last 2015, Acument had moved to CVS/Caremark for its PBM services.

307. Acument received no bill from Dr. Tumlin or Express Scripts for the Acthar prescribed to the Patient in 2011. However, in 2015 through 2016, Acument was billed for Acthar by CVS/Caremark at a discounted priced based on AWP. The discount CVS/Caremark provided Acument for the Acthar was AWP minus 15.75%.

308. Acthar paid such AWP-based amounts for the Acthar prescribed to the Patient. These payments totaled $892,017.75, which was the amount due after the Patient paid the $200 co-payment for each of the 13 prescriptions, which were filled between December 17, 2015 and December 6, 2016 at a gross cost of $68,816.75 for ten total dispensed units. As set forth on the ASAP form, the typical dosage was 10 units; however, Dr. Tumlin prescribed twice that amount

for the Acument Patient.

309. Acument suffered antitrust injury cognizable under Tennessee law because it was charged and paid an artificially inflated and fixed price for the Acthar based upon the inflated AWP for Acthar as set by Mallinckrodt and the Express Scripts Defendants, and as charged by Dr. Tumlin through his submission of the prescription through the ASAP program.

310. The Acthar was supplied directly to Acument's Patient by the Express Scripts Entities, pursuant to their exclusive agreements with Mallinckrodt. The Acthar was prescribed to the Patient by Dr. Tumlin, one of Mallinckrodt's leading KOLs in the promotion of Acthar for nephrology syndrome.

311. As set forth above, the payments made by Acument were sent to its PBM, CVS/Caremark, which then routed the payments to Express Scripts, the exclusive distributor of Acthar and Mallinckrodt's designated, exclusive agent.

312. Although Acthar was not approved to treat the Patient's condition, in 2011, Dr. Tumlin prescribed Acthar. However, neither Dr. Tumlin nor the other Defendants charged the Patient or Acument for the Acthar in 2011. Instead, the therapy ended. Then, Dr. Tumlin put the Patient back on Acthar in order to charge him and Acument the artificially inflated AWP for Acthar, and to garner monopoly profits for all Defendants charged herein.

COUNT I
ACUMENT v. ALL DEFENDANTS
MONOPOLIZATION OF
THE ACTH MARKET IN VIOLATION OF THE TTPA

313. Acument hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further allege as follows.

314. The Tennessee Trade Practices Act ("TTPA") declares unlawful, void and against public policy the following:

> All arrangements, contracts, agreements, trusts, or combinations between persons or corporations made with a view to lessen, or which tend to lessen, full and free competition in the importation or sale of articles imported into this state, or in the manufacture or sale of articles of domestic growth or domestic raw material, and all arrangements, contracts, agreements, trusts, or combinations between persons or corporations designed, or which tend, to advance, reduce, or control the price or the cost to the producer or the consumer of any such product or article….

Tenn. Code Ann. § 47-25-101.

315. The TTPA further provides relief to the following persons:

> Any person who is injured or damaged by such arrangement, contract, agreement, trust, or combination described in this part may sue for and recover, in any court of competent jurisdiction, from any person operating such trust or combination….

Tenn. Code Ann. § 47-25-106.

316. Such persons injured may recover "the full consideration or sum paid by the person for any goods, wares, merchandise, or articles, the sale of which is controlled by such combination or trust." Tenn. Code Ann. § 47-25-106.

317. In *Sherwood v. Microsoft Corp*., 2003 WL 21780975, *29 (Tenn. Ct. App. July 31, 2003), the Tennessee Court of Appeals held that indirect purchasers, like Acument, have standing to bring an action under the TTPA to recover damages resulting from price-fixing. *See Freeman Indus. LLC v. Eastman Chem Co*., 172 S. W.3d 512, 519 (Tenn. 2005).

318. Tennessee municipalities and third party payors ("TPPs"), like Acument, have standing to sue within the meaning of Tenn. Code Ann. § 47-25-106. *See Metro. Gov't of Nashville & Davidson Cnty. v. Ashland Oil, Inc*., 535 F. Supp. 328 (M.D. Tenn. 1982).

319. Acument paid the artificially inflated prices as set by Mallinckrodt and Express Scripts, and as charged by all Defendants, including Dr. Tumlin, for the Acthar prescribed to its covered Patient. As a result, Acument was injured by the conduct alleged herein.

320. The transactions at issue in this case were predominantly intrastate in character,

due to the presence of the Plaintiff, its Patient, and most of the Defendants in this State.

321. The Express Scripts Entities all forged alliances in this State, in particular in Memphis, while Mallinckrodt forged alliances with the Express Scripts Defendants and Dr. Tumlin, situate in Chattanooga.

322. The Acthar at issue was marketed and sold in this State, was prescribed in this State, was delivered in this State, was administered in this State, and was paid for in this State by the Plaintiff and its Patient.

323. Accordingly, while certain acts may have occurred outside this State, the arrangements, agreements and understandings between the Defendants had the effect of lessening competition in the sale of articles sold within this State and/or imported into this State.

324. Such arrangements, agreements and understandings between the Defendants also affected the price to consumers in this State, like Acument and its Patient.

325. As a result, the illegal conduct alleged herein substantially affected commerce within this State within the meaning of the TTPA.

326. As described in this Complaint, Mallinckrodt and Express Scripts agreed to maintain the supra-competitive prices of Acthar through the ASAP Program, limiting distribution of the drug and stifling the ability of a competitor to enter the ACTH market.

327. As a result, Defendants had "arrangements, contracts, agreements, trusts or combinations" between themselves "designated, or which tend, to advance, reduce, or control the price or the cost to the producer or the consumer" of Acthar. Tenn. Code Ann. § 47-25-101.

328. Further, to maintain these supra-competitive prices, Mallinckrodt acquired Synacthen and refused to bring it to market. Express Scripts conspired and agreed with Mallinckrodt to keep Synacthen off the market in order to maintain their monopoly profits.

329. This conduct caused Acument to pay the inflated, AWP-based prices for Acthar that were significantly greater than in a competitive market. Therefore, Acument is entitled to relief under the TTPA.

330. Acument was injured as a result of Defendants' conduct in violation of the TTPA, and hereby seeks damages in the amount of "the full consideration or sum paid" for Acthar.

331. Mallinckrodt has, and at all relevant times hereto, had monopoly power in the market for the sale of ACTH drugs in Tennessee and throughout the United States. While the genesis of this monopoly power may be natural, since 2007 Mallinckrodt has acted and conspired with Express Scripts to maintain and enhance its monopoly power in the ACTH market.

332. Dr. Tumlin has conspired and agreed with his co-Defendants to work with them maintain this monopoly by creating clinical data to promote the off-label uses of Acthar and to charge patients exorbitant AWP-based prices for Acthar.

333. As described above, Acthar's value was limited because it was the "gold standard" for treating only one condition, infantile spasms ("IS"). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 patients per year. However, by 2015, Mallinckrodt was able to grow sales of Acthar to approximately $1.1 billion.

334. As set forth above, Mallinckrodt's announced a "new strategy" was created in order to maintain and enhance its monopoly. This new strategy could not have succeeded without the involvement of Express Scripts as Mallinckrodt's exclusive agent, and providers like Dr. Tumlin who are willing and able to advance the prescriptions of Acthar for off-label uses and doses at inflated prices well any purported "value" of the medicine.

Anticompetitive Act 1: Restricted Distribution

335. On July 2, 2007, Mallinckrodt decided to restrict distribution from three wholesalers, termed Wholesalers "A", "B", and "C" in its 2007 10-K, to Express Scripts. The goal of this strategy was to lock patients into receiving Acthar through one channel and prevent a competitive product from entering the market.

336. When Mallinckrodt began its new strategy on July 16, 2007, it established the ASAP Program. *See* Exhibit "B". July 2, 2007 Urgent Product Alert H.P. Acthar Gel. The ASAP Program allowed Mallinckrodt to limit its direct distribution of the drug to the patient to just one avenue, through Express Scripts. Mallinckrodt entered an exclusive arrangement with Express Scripts to provide Acthar directly to patients, and to receive payments for Acthar directly from patients.

337. Express Scripts was Mallinckrodt's exclusive agent to operate the ASAP Program. Through ASAP, UBC facilitated all aspects of Acthar's distribution and payment as Mallinckrodt's exclusive agent. UBC's utilized Express Script's pharmacy arrangement services (Accredo), specialty drug distribution (CuraScript) and direct billing and payment (Express Scripts) functions to allow Mallinckrodt to maintain and enhance its monopoly power in the ACTH market.

338. Mallinckrodt has willfully maintained its monopoly power in the ACTH drug market through its exclusive arrangement with Express Scripts from 2007 through 2017. Having Express Scripts as its exclusive agent, Mallinckrodt was able to raise its prices tenfold initially, and nearly double in the ensuing years.

Anticompetitive Act 2: The Synacthen Acquisition

339. By 2013, Mallinckrodt had identified a competitive threat to its monopoly power,

despite its exclusive arrangements with Express Scripts. When Novartis decided to sell Synacthen Depot to a competitor, Mallinckrodt acted to protect its monopoly. Recognizing that the entry of Synacthen to the ACTH market would threaten its monopoly power, Mallinckrodt first attempted to buy the rights to Synacthen in 2009, it was unable to do so.

340. When Novartis agreed to sell Synacthen to Retrophin in 2013, Mallinckrodt disrupted the bidding process for Synacthen by intervening at the last minute to pay multiple times what had been offered by Retrophin. Retrophin had agreed to buy Synacthen for $16 million, Mallinckrodt paid $135 million. It licensed the U.S. rights to Synacthen from Novartis, but did not bring this viable synthetic alternative to market. Instead, it acted only to eliminate the nascent competitive threat to its monopoly posed by an independently owned Synacthen.

341. This conduct contributed to Mallinckrodt's maintenance of monopoly power. Both anticompetitive acts – the exclusive arrangement with Express Scripts and the Synacthen acquisition had the purpose and effect of suppressing rather than promoting competition in the ACTH market. Mallinckrodt was able to raise prices at will.

342. But Mallinckrodt could not get away with keeping Synacthen off the market without the substantial assistance and agreement of Express Scripts, who traded exclusivity and a share of monopoly profits for withholding its demonstrated power and leverage to reduce drug prices.

343. Mallinckrodt used its enhanced monopoly power to inflate the prices of Acthar as set forth herein. Today the prices stand at over $43,000.

344. The challenged conduct caused Acument to pay artificially inflated prices for Acthar in the ACTH drug market.

345. There is no procompetitive justification for the conduct of Mallinckrodt, Express

Scripts or Dr. Tumlin. Rather these Defendants combined to lock Acthar into a restricted distribution model, overseen by the ASAP program, to ensure enhanced monopoly profits for all of them. The Synacthen acquisition only prevented competition, and preserved the enhanced monopoly power Mallinckrodt enjoyed due to Express Scripts' collusion.

Plaintiff is an Indirect Purchaser of Acthar Harmed by Defendants' Anti-Competitive Conduct

346. Acument has been indirectly injured in its business and property by reason of Mallinckrodt's unlawful monopolization in concert with Express Scripts and Dr. Tumlin. Acument's injuries consist of paying higher prices to purchase Acthar than it would have paid absent the conduct of Mallinckrodt and its exclusive agent, Express Scripts. Acument's injuries are the type of harm the Tennessee laws were designed to prevent and flow from which makes Mallinckrodt's, Express Scripts' and Dr. Tumlin's conduct unlawful.

347. The product ships from Mallinckrodt's agent directly to the patient. Payments flow directly from Rockford to Express Scripts, via CVS Caremark, for the benefit of Mallinckrodt. Express Scripts deducts its agreed-upon share of Acument's payments before forwarding them to Mallinckrodt.

348. As described herein, Defendants' acts and practices constitute monopoly maintenance in violation of the Tennessee antitrust laws.

WHEREFORE, Acument demands that judgment be entered in its favor, and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT II
ACUMENT v. ALL DEFENDANTS
ANTI-COMPETITIVE AGREEMENTS IN UNREASONABLE
RESTRAINT OF TRADE IN VIOLATION OF THE TTPA

349. Acument hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further allege as follows.

350. As set forth above, Mallinckrodt has entered into exclusive agreements with the agent for its largest customers, Express Scripts. These agreements preserved and extended Mallinckrodt's monopoly power, and allowed both Mallinckrodt and Express Scripts to raise and fix the prices for Acthar to Express Scripts' direct clients, including Rockford, and indirect clients, like Acument.

351. These agreements violated the TTPA, § 47-25-101 et seq., as set forth herein.

The Role of Express Scripts in the Specialty Drug Market

352. The maintenance of Mallinckrodt's monopoly over the ACTH market would not be possible without its agreement in restraint of trade with Express Scripts.

353. As described above, Express Scripts is one of the largest PBMs and thus one of the largest buying agents of pharmaceuticals in the country.

354. It has substantial buying power, and therefore market power, as a result of its position as one of the largest purchasers of pharmaceuticals in the country, and one of largest representatives of health plans that purchase pharmaceuticals for their beneficiaries.

355. The Express Scripts Entities have developed a consolidated network of specialty pharmaceutical management, distribution and reimbursement that creates a direct pipeline between the manufacturer and the patient. The Express Scripts Entities operate a specialty pharmaceutical distributor, a specialty pharmacy, and a reimbursement HUB, all of which operate in service of the specialty drug manufacturer [here, Mallinckrodt] concomitantly with

Express Scripts' service as a PBM for health plans and patients.

356. Because Express Scripts represents more than 80% of pharmaceutical buyers in the United States, it has the unique position to use its market power to push back against high pharmaceutical prices, especially specialty drugs like Acthar. Express Scripts has demonstrated its ability to wield its market power to effectuate lower costs for high priced specialty drugs.

357. The above-described example of Turing's Daraprim is stark in that Express Scripts used its market power to produce a comparable drug for $1. Instead of the $750.00 per pill charged by Turing, Express Scripts charges its clients $1. Instead of one year's course of treatment costing $361,000, it costs less than $100 to Express Scripts customers.

Express Scripts' Agreement with Mallinckrodt to Raise and Fix Prices for Acthar

358. In 2007, when Express Scripts entered its exclusive arrangement with Mallinckrodt's predecessor Questor, it did not push back against Questcor's decision to raise prices. Instead, when confronted with the price increase, Dr. Miller asserted that "[t]he increase was a manufacturing decision. I can't comment on it." Id.

359. There was no legitimate business justification on the part of Express Scripts to agree to charge the inflated end payor prices set by Questcor to its clients, but it so agreed.

360. By 2015, Acument contracted with CVS Caremark for the provision of specialty drugs, like Acthar, to its employee beneficiaries. CVS Caremark simply charged the same inflated AWP-based prices based on the prices set by Mallinckrodt in agreement with Express Scripts, as the product continued to flow directly from Express Scripts to the patients of other PBMs, like CVS Caremark. As a result, the Mallinckrodt-Express Scripts' agreement to fix prices preserved and enhanced Mallinckrodt's monopoly power and injured payors like Acument being charged the same artificially inflated prices for Acthar.

361. As a result, Express Scripts conspired and agreed with Mallinckrodt to fix and charge artificially inflated prices for Acthar to CVS Caremark clients, like Acument.

362. At all relevant times, Mallinckrodt's exclusive agreements with Express Scripts assisted Mallinckrodt in: (a) effectively excluding less expensive, potentially superior competitive products from the ACTH drug market; (b) maintaining Mallinckrodt's dominant market share and monopoly power in the ACTH drug market; (c) maintaining prices at artificially high levels for Acthar; and (d) otherwise reaping the benefits of its Mallinckrodt's enhanced monopoly power.

363. There is no procompetitive justification for the conduct of either Mallinckrodt or Express Scripts.

364. Acument has been injured in its business and property by reason of the alleged collusion and conspiracy between Mallinckrodt and Express Scripts, its exclusive agent, which had the purpose and effect of raising and stabilizing inflated prices for Acthar. Express Scripts facilitated, enabled, assisted, and furthered Mallinckrodt's substantial foreclosure and exclusion of competition and monopolization of the ACTH drug market.

365. Acument's injuries consist of paying higher prices to purchase Acthar than they would have paid absent the unlawful conduct of Mallinckrodt and Express Scripts. Acument's injuries are the type the Tennessee antitrust laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

366. Defendants' acts and practices constitute anti-competitive agreements in unreasonable restraint of trade in violation of the Tennessee antitrust laws.

WHEREFORE, Acument demands that judgment be entered in its favor, and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys'

fees, and such other relief deemed just and appropriate by this Court.

COUNT III
ACUMENT v. ALL DEFENDANTS
VIOLATIONS OF THE TENNESSEE CONSUMER FRAUD LAWS

367. Acument hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows.

368. The Tennessee Consumer Protection Act of 1997 ("TCPA") creates a private right of action for consumers to sue for violations thereof. Tenn. Code Ann. § 47-18-101, et. seq.

369. The TCPA was enacted "to protect consumers and legitimate business enterprises from those who engage in unfair or deceptive acts or practices in the conduct of any trade or commerce . . ., to encourage and promote the development of fair consumer practices; [and] . . . to declare and to provide for civil legal means for maintaining ethical standards of dealing between persons engaged in business and the consuming public to the end that good faith dealings between buyers and sellers at all levels of commerce be had in this state . . ." Tenn. Code Ann. § 47-18-102.

370. A consumer is defined as "any natural person who seeks or acquires by purchase, … or other disposition, any goods…". Tenn. Code Ann. § 47-18-103(2). "Person" includes corporations, like Acument. Tenn. Code Ann. § 47-18-103(13). Therefore, Acument is both a consumer and "legitimate business enterprise" for purposes of the TCPA.

371. The consumer transaction at issue here – the sale of Acthar – took place in the conduct of trade or commerce within Tennessee.

372. The TCPA "is to be liberally construed to protect consumers and others from those who engage in deceptive acts or practices." *Morris v. Mack's Used Cars,* 824 S.W.2d 538, 540 (Tenn. 1992); Tenn. Code Ann. § 47-18-102(2).

373. A plaintiff-consumer suing under the TCPA must prove two things: (1) that the defendants engaged in unfair or deceptive acts or practices declared unlawful by the TCPA, and (2) that the defendants' conduct caused an ascertainable loss of money or property. Tenn. Code Ann. § 47-18-109(a)(1).

374. Tenn. Code Ann. § 47-18-104(a) makes unlawful any "unfair or deceptive acts or practices affecting the conduct of any trade or commerce".

375. Tenn. Code Ann. § 47-18-104(b) defines "unfair or deceptive acts or practices" include the following, among others:

> (2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services.
>
> (3) Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by another.
>
> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have.
>
> (7) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;
>
> (8) Disparaging the goods, services or business of another by false or misleading representations of fact.
>
> (11) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions.

376. Defendants engaged in the following unfair and deceptive acts or practices, which violate the aforesaid provisions of the TCPA:

a. By entering into the exclusive distribution arrangement described herein in 2007, and not disclosing the same to Acument, especially in the ASAP form given to Acument's beneficiary and Dr. Tumlin, Defendants engaged in unfair or deceptive acts, made misrepresentations and omissions of material fact, to Plaintiff that impeded Plaintiff's efforts to contain its

costs for specialty drugs like Acthar, and then sending bills for Acthar which charged the artificially inflated prices which Defendants agreed amongst themselves to charge Plaintiff. This caused at least a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval and/or certification of Acthar sold by Mallinckrodt, the affiliation, connection or association between the various Defendants and the roles in the Acthar scheme alleged, misrepresented the same, and/or constituted unfair or deceptive conduct which created a likelihood of confusion or a misunderstanding by Plaintiff.

b. Defendants conspired and agreed to adopt the above-described ASAP program and the ASAP form (Exhibit "A" hereto) in 2007, and to maintain the Program and form through 2015-16 (when Plaintiff paid for Acthar), in order to mislead and deceive Acument and its beneficiary about Express Scripts' direct role as the "hub" of patient care as it concerns the medical conditions for which Acthar is indicated, and to bypass Plaintiff's efforts to contain and reduce costs for specialty drugs.

c. Starting in July 2007, Mallinckrodt issued a misleading and deceptive announcement about its new distribution strategy, but the announcement failed to disclose that more than pharmacy distribution was being handed over to Express Scripts; all aspects of distribution, pricing and product sales were now being handled by Express Scripts, and its wholly-owned subsidiaries, as part of a "hub" of services for which Mallinckrodt contracted.

d. Express Scripts made material misrepresentations and engaged in deception about its contractual relationships with Mallinckrodt and the real reasons for the exorbitant Acthar price increases between August 2007 and 2016. In 2007, when asked directly about the huge price increase, Dr. Miller of Express Scripts' misled and deceived the public by claiming "[t]he increase was a manufacturing decision. I can't comment on it." In truth, it was a joint decision by Defendants, reflected in contracts, agreements and understandings between them.

e. Express Script's Dr. Miller and Express Scripts remained silent about the truth about Acthar's "value" for years, so that Express Scripts could continue to charge false, misleading and excessive prices for Acthar to payors like Plaintiff. In fact, it was not until the spring of 2017 – after Plaintiff made its first payment for Acthar—that Express Scripts admitted Acthar was not worth the price Express Scripts and Mallinckrodt were charging for it. That year, ESI's Senior Vice President of Supply Chain and Specialty Pharma, Everett Neville, stated, "I don't think [Acthar is] a very great [drug] – it's a pretty poor drug with a very limited need and certainly [ESI's Chief Medical Officer, Dr,] Steve[Miller] could

comment." Mr. Neville went on to say, "I think [Dr. Miller] and I both would agree, and I think everybody in our company would agree, that [Acthar] is vastly overpriced for the value.". Mr. Neville stated that he "personally told [Mallinckrodt's] management team that their drug is hugely overpriced and that he "know[s] [Dr. Miller] has as well." In the same public setting, Dr. Miller stated, "[i]f you look at the data, the indications for the drug are . . . in the compendium, it's listed under a lot of indications, its real use should be very, very limited. It's an old drug. There's better products in the marketplace and so we're going to continue to be very vigilant in our utilization management." These revelations came far too late to save Plaintiff from being overcharged for Acthar, and demonstrate that Defendants conspired and agreed to commit acts or practices in violation all of the above-described sub-sections of 73 Pa. Stat. Ann. §§201. For instance, Express Scripts misled Plaintiff and deceived Plaintiff about its approval of Acthar and the benefits of Acthar as a valuable specialty drug "worth" what it and Mallinckrodt were charging, in relation to other drugs and treatments (in violation of above listed subsections (5) and (7) of the TCPA).

f. Defendants misled and deceived Acument and the public about their direct relationship, their joint decision to raise the prices of Acthar, and the lack of value of Acthar for the prices being charged, in order to intentionally and deceptively charge false, misleading and excessive prices for Acthar, during the period between 2007 (when they entered into their exclusive distribution arrangement), through 2013 (when Mallinckrodt acquired Synacthen in 2013 and Express Scripts did nothing about it), and up to at least 2017 when Express Scripts began to tell the truth. Express Scripts then offered discounts off the inflated prices of Acthar which were far less than the discounts offered for either brands or generics, while failing to disclose the truth about the pricing disparity for Acthar (even with the discounts), thereby misleading Plaintiff as to the reasons for, existence of, or amounts of the Acthar price reductions, including the provision of free Acthar as part of an undisclosed "buy 1, get 1" program for doctors, in violation of sub-section (11).

g. In their promotion of Acthar to treat diseases other than IS, like the DM/PM suffered by Acument's beneficiary, Defendants have disparaged the goods, services or business of other sellers of drugs that treat such diseases more effectively and safely, and for much less money, by false or misleading representations of fact.

h. Defendants acts or practices, including the failures to act and to speak the truth in the face of false, misleading and deceptive statements about Acthar's pricing, distribution and value, constitute unfair and deceptive acts or practices.

377. The acts and practices described herein demonstrate that Mallinckrodt, Express Scripts and Dr. Tumlin acted unlawfully within the meaning of the TCPA such that Acument may be awarded up to three times its actual damages sustained, and such additional relief as deemed necessary or proper. These damages consist of, inter alia, the difference between the true price of Acthar before Mallinckrodt engaged with Dr. Tumlin in at least 2011 and with Express Scripts beginning in 2007 to artificially inflate the "average wholesale price" of Acthar, as required by contract to be charged, and the inflated prices of Acthar charged to Plaintiff in 2015-2016.

378. Acument seeks relief against Mallinckrodt, Express Scripts and Dr. Tumlin for their unfair and deceptive conduct which allowed Defendants to raise and fix the prices of Acthar at supra-competitive levels, and to maintain Mallinckrodt's monopoly power in the market for ACTH drugs allowing unfettered price increases.

379. Mallinckrodt and Express Scripts agreed to raise the prices of Acthar, and Dr. Tumlin agreed to charge Acument and its beneficiary these prices.

380. Acument was injured as a direct and proximate result of the Defendants' conduct in violation of the TCPA sections above, and hereby seeks damages.

WHEREFORE, Acument demands that judgment be entered in its favor, and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT IV
ACUMENT v. ALL DEFENDANTS
UNJUST ENRICHMENT

381. Acument hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows.

382. This Count alleges unjust enrichment against all Defendants.

383. Acument's covered beneficiary received direct shipments of Acthar from Mallinckrodt via CVS Caremark. In exchange for Acthar, Acument made direct payments to CVS Caremark for the benefit of Mallinckrodt, via Dr. Tumlin and Express Scripts. Indeed, such payments were transferred by CVS Caremark to Mallinckrodt through its exclusive agent, Express Scripts pursuant to a prescription written by Dr. Tumlin that charged the inflated Acthar AWP. Like Express Script, CVS Caremark reduced its payment to Mallinckrodt via Express Script by a certain amount previously agreed to by Mallinckrodt, Express Scripts and CVS Caremark. The amount charged by Mallinckrodt for the Acthar was the amount paid by Acument, less the applicable co-pay paid by the Patient.

384. The amounts paid by Acument were valuable to Mallinckrodt, Express Scripts and Dr. Tumlin, and all Defendants were unjustly enriched by such payments, in that, the prices charged by Defendants at extremely high prices were valuable and beneficial to all Defendants.

385. By engaging in the conduct described in this Complaint, Defendants have knowingly obtained benefits from Acument, namely grossly inflated payments, revenues and profits from their coordination all aspects of Acument's receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for the Defendants to retain such benefits.

386. By engaging in the unlawful conduct described herein, Defendants have been knowingly enriched by the amount charged for Acthar over and above what it could have charged in a competitive market.

387. Defendants were able to extract exorbitant revenue from Acument beyond what they could have received in the absence of such unlawful conduct. This conduct violated

Tennessee law and, as such, interfered with the legally protected interests of Acument.

388. Acument is therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

WHEREFORE, Acument demands that judgment be entered in its favor, and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT V
ACUMENT v. ALL DEFENDANTS
FRAUD

389. Acument hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further allege as follows.

390. Defendants' acts violate the common law against negligent misrepresentation and fraud.

391. In setting the inflated, AWP-based prices for Acthar, which prices Acthar paid, the Defendants made material misrepresentations that those prices represented the purported "average" of "wholesale prices" for Acthar, or some price reasonably related thereto, which they did not. Defendants also misrepresented that the inflated AWP prices for Acthar represented the actual value of the product in the marketplace, which they did not.

392. These representations were material to the transactions at hand in that Acument used and relied upon these AWP prices, as set forth in its PBM contracts, as the amount to pay and/or reimburse for Acthar.

393. As set forth more fully above, these prices were artificial prices, unrelated to any actual, reasonable price in the marketplace, or the actual value of Acthar, but created and

manipulated by the Defendants for the purpose of generating exorbitant revenue, thus constituting false representations which the Defendants knew or, in the absence of recklessness, should have known to be false.

394. The Defendants made these false representations about the prices of Acthar with the intent of misleading Acument into relying on the prices as real and fact-based prices, rather than artificially inflated prices.

395. Acument justifiably relied upon these false misrepresentations in purchasing and/or reimbursing Acthar at the amount charged by Medco/Express Scripts and CVS Caremark based on the prices set by Mallinckrodt and Express Script by contract, as charged by Dr. Tumlin. These prices were included in Acument's PBM contract, and thus Acument was obligated to pay them.

396. The prices for Acthar set forth in such Acument's contracts with Medco/Express Scripts and CVS Caremark were prices set by Mallinckrodt and Express Scripts as provided by the contracts between them. As such, all Defendants communicated these false AWP prices for Acthar directly to Acument for the Acthar sold to Acument's Patient by Dr. Tumlin's prescription.

397. Defendants knew or should have known that Acument was required to pay the inflated AWPs for Acthar by its PBM agreements, and thus intended that Acument reasonably rely on such prices as the "average wholesale prices" for Acthar.

398. As a direct and proximate result of the false representations of the Defendants, as set forth above, Acument was harmed in that they were unaware of the artificial, inflated prices of Acthar, would not have paid and/or reimbursed the artificially inflated prices for Acthar had they known of the false representations and, in fact, overpaid for the Acthar because of the false

representations.

WHEREFORE, Acument demands that judgment be entered in its favor, and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VI
ACUMENT v. ALL DEFENDANTS
CONSPIRACY TO DEFRAUD/CONCERTED ACTION

399. Acument hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further allege as follows.

400. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to Acument, and continuing thereafter until the present, Defendants and other unnamed co-conspirators, between and among themselves and others, entered into an agreement and/or otherwise engaged in a continuing conspiracy to defraud and deceive Acument by causing them to pay more for Acthar than they otherwise would have paid in the absence of the Defendants' conspiracy and concerted action.

401. Pursuant to the unfair and deceptive scheme to distribute, market and sell Acthar to derive substantial profits, and the conspiracy alleged herein, and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to deceive Acument, and acted or took substantial steps in furtherance of the conspiracy. Those acts include the following:

a. discussing and agreeing among themselves and with their co-conspirators that they would directly control the prices at which Acument paid for Acthar;

b. discussing and agreeing among themselves and with their co-conspirators that they would increase the prices at which Acument paid for Acthar;

c. discussing and agreeing among themselves and with their co-conspirators that they would directly control the ASAP program materials and website which

enrolled patients into an exclusive distribution network for the administration of Acthar, allowing Defendants to conduct their unfair pricing scheme for Acthar;

d. discussing and agreeing among themselves and with their co-conspirators that they would directly control the exclusive distribution network for Acthar through the ASAP Program;

e. discussing and agreeing among themselves and with their co-conspirators that they would rely on employees to promote the ASAP Program through the marketing alleged herein;

f. discussing and agreeing among themselves and with their co-conspirators that they would participate in the affairs of the ASAP program by using a fraudulent scheme to market and sell Acthar at inflated prices; and

g. discussing and agreeing among themselves and with their co-conspirators that they would conceal and suppress the truth about the Acthar inflated prices, the monies earned from payors, like Acument, and their exclusive arrangement to maintain and enhance Mallinckrodt's monopoly power as alleged herein.

402. In addition to the specific facts set forth above, it is alleged the Defendants and their co-conspirators engaged in conspiratorial meetings, among the purposes of which meetings were to discuss the importance of controlling the direct distribution, marketing, sale, prescription and administration of Acthar to Acument and its covered Patient, and deriving substantial profits from these activities.

403. The Defendants performed the conspiratorial acts set forth herein intending to injure payors of Acthar, like Acument, by causing them to pay inflated prices so that the Defendants could derive substantial profits.

404. The Defendants performed the acts alleged herein in furtherance of the common plan or design for the conspiracy with intent and/or with knowledge of the injury and damage it would cause to the Acument, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences.

405. As a direct and proximate result of the Defendants' conspiracy as alleged herein,

Acument have been injured and damaged, and the Defendants are jointly and severally liable for such injuries and damages.

WHEREFORE, Acument demands that judgment be entered in its favor, and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

PRAYER FOR RELIEF

WHEREFORE, Acument requests the Court to enter the following relief:

a. Declare unlawful the acts and practices alleged herein, enjoin the Defendants from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;

b. Enter judgment against all Defendants for the violations alleged herein;

c. Award the actual damages incurred by Acument as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;

d. Award statutory damages set forth herein under the statutory claims alleged;

e. Award multiple damages by operation of law;

f. Award punitive damages;

g. Award Acument the costs of this action, including reasonable attorneys' fees, and, where applicable, expert fees; and

e. Award such other and further relief as the Court may deem just and appropriate.

JURY DEMAND

Acument demands a trial by jury of all issues so triable in this cause.

Respectfully submitted,

By: _____

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EXHIBIT A

H.P. Acthar® GEL
(repository corticotropin injection) 80 U/mL

FAX: 1-877-937-2284

Acthar Start Form

Please complete Start Form and fax toll-free
TEL: 1-888-435-2284
Monday through Friday (8:00 am to 9:00 pm EST)
Saturday (9:00 am to 2:00 pm)

1. PATIENT INFORMATION

Patient has been notified of referral ☐ YES ☐ NO

PATIENT FIRST NAME | PATIENT MIDDLE INITIAL | PATIENT LAST NAME | DATE OF BIRTH | GENDER

HOME ADDRESS | CITY | STATE | ZIP

SHIPPING ADDRESS (IF NOT HOME ADDRESS) | CARE OF (IF NOT ADDRESSED TO PATIENT) | CITY | STATE | ZIP

HOME PHONE | MOBILE | OK TO TEXT | BEST TIME TO CALL | PREFERRED LANGUAGE IF NOT ENGLISH

EMAIL ADDRESS | PATIENT REPRESENTATIVE | RELATIONSHIP | TELEPHONE

2. INSURANCE INFORMATION (PLEASE INCLUDE COPIES OF CARDS)

PHARMACY BENEFITS | SUBSCRIBER ID # | GROUP # | TEL #

PRIMARY MEDICAL INSURANCE | POLICY HOLDER | RELATIONSHIP | SUBSCRIBER ID # | GROUP # | TEL #

3. HEALTHCARE PROVIDER (HCP) INFORMATION

HCP FIRST NAME | HCP LAST NAME | HCP MIDDLE INITIAL | NPI # | GROUP NPI # (IF APPLICABLE) | STATE LICENSE #

SPECIALTY: NEPHROLOGY | NEUROLOGY | PULMONOLOGY | RHEUMATOLOGY | OPHTHALMOLOGY | OTHER _____ IF OTHER PLEASE INDICATE

FACILITY NAME | TELEPHONE | FAX

ADDRESS | CITY | STATE | ZIP

OFFICE CONTACT NAME | CONTACT TELEPHONE | EMAIL ADDRESS | PREFERRED METHOD OF COMMUNICATION

4. PRESCRIPTION: H.P. ACTHAR® GEL

NDC# 63004-8710-1 5 mL multidose vial containing 80 USP units per mL

PRIMARY DIAGNOSIS: _____ **ICD-10:** _____

INITIATE PATIENT WITH:

DOSE: _____ UNITS ML **SCHEDULE/FREQUENCY:** _____ | **QUANTITY OF 5 ML MULTIDOSE VIALS:** _____ **REFILLS:** _____ | **ROUTE OF ADMINISTRATION:** INTRAMUSCULAR SUBCUTANEOUS

ADDITIONAL SPECIAL INSTRUCTIONS, OR TAPER DOSE, IF APPLICABLE: _____ **ALLERGIES:** _____

SUPPLIES:

SYRINGE SIZE: 1 mL 3 mL Other size ____ **QUANTITY:** ____ **NEEDLE SIZE:** 20 g needle, 1 inch 23 g needle, 1 inch 25 g needle, 1 inch Subcutaneous only 25 g needle, 5/8 inch (other): ___ **QUANTITY:** ____

PATIENT WEIGHT (FOR WEIGHT-BASED DOSING ONLY): _____ **SUPPLY REFILLS:** _____ **SHARPS CONTAINER:** _____ **OTHER SUPPLIES:** _____

HOME INJECTION TRAINING SERVICES (HITS)

By initialing here (original required) I request that company-funded HITS services be arranged for my patient. I understand that HITS is for one instruction visit only and NOT a home health nursing service. I also understand that all reasonable efforts will be made to schedule the HITS training visit within 24 hours of the patient's receipt of drug shipment.

INITIALS | DATE

5. PRESCRIPTION, CONSENT AND STATEMENT OF MEDICAL NECESSITY: HCP SIGNATURE REQUIRED

I certify that H.P. Acthar® Gel is medically necessary for this patient and that I have reviewed this therapy with the patient and will be monitoring the patient's treatment. I verify that the patient and healthcare provider information on this enrollment form is complete and accurate to the best of my knowledge. I understand that I must comply with my practicing state's specific prescription requirements such as, e-prescribing, state specific prescription form, fax language, etc. Non-compliance of state specific requirements could result in outreach to me by the dispensing pharmacy.

I authorize United BioSource Corporation ("UBC"), the current operator of the Acthar Support and Access Program ("Program"), and other designated operators of the Program, to perform a preliminary assessment of benefit verification for this patient and furnish information requested by the patient's insurer that is available on this form. I understand that insurance verification is ultimately the responsibility of the provider and third-party reimbursement is affected by a variety of factors. While UBC tries to provide accurate information, they and Mallinckrodt make no representations or warranties as to the accuracy of the information provided.

I understand that representatives from the Program or UBC may contact me or my patient for additional information relating to this prescription. I acknowledge and agree that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy

HCP Prescriber Signature - Please sign ONE LINE below

DISPENSE AS WRITTEN | DATE | SUBSTITUTIONS ALLOWED | DATE

Prescriber signature required to consent and validate prescriptions. Prescriber attests that this is her/his signature. NO STAMPS. By signing, I certify that the above is medically necessary.

For Patient: _____ **DOB:** _____

6. DIAGNOSIS AND MEDICAL INFORMATION

Diagnosis

Please select diagnosis and responses to associated questions

❑ **Ankylosing spondylitis**

❑ **Dermatomyositis**

❑ **Infantile spasms**

Has diagnosis been confirmed by EEG?

❑ YES ❑ NO

Patient's weight: _____

Requested drug delivery date: _____

❑ **Multiple sclerosis**

Is Acthar to be used to treat an acute exacerbation?

❑ Exacerbation ❑ Other_____ Must check one

Onset of acute exacerbation Date:_____

❑ **Optic neuritis**

❑ **Polymyositis**

Proteinuria in nephrotic syndrome

Please indicate etiology:

❑ Focal segmental glomerular sclerosis (FSGS)

❑ IgA nephropathy (IgAN)

❑ Lupus nephritis

❑ Membranous nephropathy (MN)

❑ Other: _____

❑ **Psoriatic arthritis**

❑ **Rheumatoid arthritis**

❑ **Sarcoidosis**

❑ **Systemic lupus erythematosus**

Is Acthar to be used to treat an acute exacerbation?

❑ YES ❑ NO Must check one

Lupus nephritis?

❑ YES ❑ NO

❑ **Uveitis**

❑ **Other diagnosis** _____

7. HISTORY OF CORTICOSTEROID USE (IF APPLICABLE) PLEASE ADD DETAILS IN SECTION 8 BELOW

Please check all that apply

A corticosteroid was tried with the following response(s):

❑ Corticosteroid use failed, but same response not expected with Acthar

❑ Patient hypersensitive or allergic to corticosteroids

❑ Patient intolerant to corticosteroids

❑ Other: _____

OR

A corticosteroid was not tried due to the following response(s):

❑ Corticosteroid use is contraindicated for this patient

❑ Intravenous access is not possible for this patient

❑ Patient has known intolerance to corticosteroids

❑ Other:_____

8. CONCURRENT MEDICATIONS

9. RELEVANT TREATMENT HISTORY (INCLUDING RECENT STEROID HISTORY)

Therapy Name	Dose	Start Date	Stop Date (if applicable)	Explain Outcome With Detail (ex. type of outcome)

(Attach additional pages as necessary)

OTHER RELEVANT CLINICAL INFORMATION

HCP SIGNATURE: REQUIRED FOR DOCUMENTATION

NAME SIGNATURE DATE

H.P. Acthar® GEL
(repository corticotropin injection) 80 U/mL

For completion by patient or their representative

Patient Name:_____ **DOB:**_____

10. PATIENT AUTHORIZATION(S)

For Patient Review and Completion. If patient is not available, authorization will be obtained from patient by Acthar Support and Access Team upon receipt of referral.

By signing this authorization, I authorize my physician(s), my health insurance company, my pharmacy providers and Mallinckrodt ARD Inc., the distributor of Acthar ("Mallinckrodt"), and its agents, authorized designees and contractors, including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support and Access Program on behalf of Mallinckrodt (collectively, "Designated Parties"), to use and disclose to other Designated Parties health information relating to my medical condition, treatment, and insurance coverage (my "Health Information") in order for them to (1) provide certain services to me, including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injection training, (2) provide me with support services and information associated with my Acthar therapy, (3) for internal business purposes, such as for marketing research, internal financial reporting and operational purposes, and (4) to carry out the Designated Parties' respective legal responsibilities.

Once my Health Information has been disclosed to the Designated Parties, I understand that it may be re-disclosed by them and no longer protected by federal and state privacy laws. However, the Designated Parties agree to protect my Health Information by using and disclosing it only for the purposes detailed in this authorization or as permitted or required by law.

I understand that I may refuse to sign this authorization and that my physician and pharmacy will not condition my treatment on my agreement to sign this authorization form, and my health plan or health insurance company will not condition payment for my treatment, insurance enrollment or eligibility for insurance benefits on my agreement to sign this authorization form. I understand that my pharmacies and other Designated Parties may receive payment in connection with the disclosure of my Health Information as provided in this authorization. I understand that I am entitled to receive a copy of this authorization after I sign it.

I may revoke (withdraw) this authorization at any time by mailing a letter to Acthar Support and Access, 255 Technology Park, Lake Mary, FL 32746. Revoking this authorization will end further disclosure of my Health Information to Designated Parties by my pharmacy, physicians and health insurance company when they receive a copy of the revocation, but it will not apply to information they have already disclosed to the Designated Parties based on this authorization. I also know I may cancel my enrollment in a patient support program at any time in writing by contacting Mallinckrodt via fax at 877-937-2284.

This authorization is in effect for 1 year or until the conclusion of any ongoing coverage support, whichever is longer, once I have signed it unless I cancel it before then.

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE

I authorize Mallinckrodt and its agents to receive, use, and disclose my health information relating to my medical condition, treatment, insurance coverage, and contact information from me, my healthcare providers, my pharmacies, and my health insurance company in order to (1) contact me about participation in Acthar patient programs, (2) provide me with educational or other informational materials, (3) administer its education and other patient-related programs, (4) conduct surveys that request my feedback, and (5) for Mallinckrodt to carry out its legal responsibilities in connection with these education and support programs. I agree to let Mallinckrodt or its agents contact me in the future about these offerings. Once my health information has been disclosed to the education, informational and/or support program I choose to participate in, I understand that it may be redisclosed by Mallinckrodt or its agents, and they are authorized to use or disclose this information in the manner described here and as permitted by this authorization or as otherwise permitted or required by law, and that federal and state privacy laws may no longer protect the information. However, Mallinckrodt and its agents agree to protect my health information by using and disclosing it only for the purposes described in this authorization or as permitted or required by law. This authorization will remain in effect until I cancel it which I may do so at any time by contacting Mallinckrodt via fax at 877-937-2284. Cancelling this authorization will end further use or disclosure of my health information by Mallinckrodt or its agents (except to the extent that such parties took actions based on this authorization prior to my revocation). If I withdraw my permission, I know that this means I may no longer receive information on supplemental education or support programs. Once I withdraw my permission, no new information will be disclosed to Mallinckrodt or its agents, but Mallinckrodt and its agents may continue to use the information that was collected before I withdrew my permission as permitted by this authorization or as otherwise permitted or required by law. I may request a copy of this signed authorization.

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE

Acthar Support and Access Program
FAX: 1-877-937-2284 TEL: 1-888-435-2284

INDICATIONS AND USAGE

- **Infantile spasms:** H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- **Multiple Sclerosis:** H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- **Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- **Dermatologic Diseases:** Severe erythema multiforme, Stevens-Johnson syndrome
- **Allergic States:** Serum sickness
- **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- **Respiratory Diseases:** Symptomatic sarcoidosis
- **Edematous State:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origins

WARNINGS AND PRECAUTIONS

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-axis (HPA) may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA suppression after stopping treatment
- Cushing's Syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Blood pressure, sodium and potassium levels may need to be monitored
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression, and psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity
- There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

ADVERSE REACTIONS

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve

Other adverse events reported are included in the full Prescribing Information.

Please see accompanying full Prescribing Information.

Mallinckrodt Pharmaceuticals

EXHIBIT B

QUESTCOR

URGENT PRODUCT ALERT
H.P. Acthar® Gel

July 2, 2007

Dear Healthcare Professional,

As you know, H.P. Acthar® Gel (repository corticotropin injection) plays a critical role in many inpatient and outpatient treatment regimens. **Effective August 1, 2007, Acthar Gel (NDC # 63004-7731-1) will be available exclusively through Specialty Pharmacy Distribution.** Acthar Gel will no longer be available from traditional pharmaceutical wholesalers or retail pharmacies. Please be sure to share this information appropriately with your staff and patients.

For Hospital Stock Orders

Beginning July 16, 2007, hospitals should place all stock orders with CuraScript Specialty Distribution **(877-599-7748)**. We suggest that appropriate personnel at your facility contact CuraScript Specialty Distribution **(877-599-7748)** as soon as possible to establish an account.

Planning for Patient Discharge – Outpatient Prescriptions

Beginning July 16, 2007, when treatment with Acthar Gel is initiated in a hospital setting with the intent to continue after discharge, it is imperative that the outpatient prescription order be placed immediately after treatment initiation to ensure an uninterrupted supply of Acthar Gel at discharge. Beginning July 16, 2007, please contact the following support and access program to get prescriptions filled and for assistance with reimbursement:

Acthar Support & Access Program (ASAP)

- **PHONE: 888-435-2284**
- **FAX: 877-937-2284**

More information and referral forms can be obtained at **www.acthar.com.**

Filling Prescriptions

Please tell your patients currently having Acthar Gel prescriptions filled at retail pharmacies to immediately confirm the pharmacy has stock on hand for their remaining refills. Beginning July 16, 2007, all new Acthar Gel prescriptions should be submitted to the Acthar Support & Access Program **(PHONE: 888-435-2284; FAX: 877-937-2284).**

Questcor is committed to providing uninterrupted availability of Acthar Gel for patients who critically need it. This change in Acthar Gel distribution and the creation of the Acthar Support & Access Program is an important part of this mission.

Sincerely,

Steve Cartt, Executive Vice President, Corporate Development
Questcor Pharmaceuticals

EXHIBIT C

FACTS ABOUT H.P. ACTHAR GEL®

Updated June 29, 2018

H.P. Acthar® Gel Value to Patients

Our mission at Mallinckrodt is Managing Complexity. Improving Lives. Our employees live this mission every day, and we're focused on providing safe, effective treatments that make a difference in the lives of patients, especially those with severe and critical conditions.

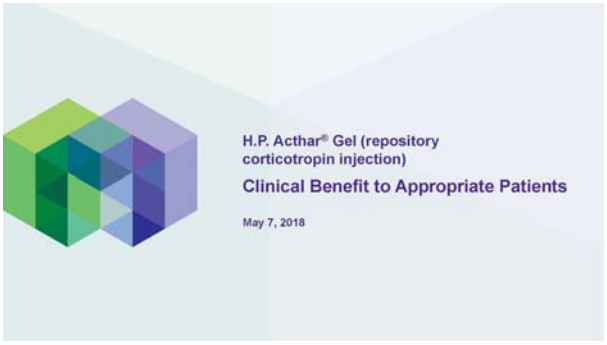
A number of media outlets and other external parties have made misleading and inaccurate allegations about H.P. Acthar Gel (repository corticotropin injection) and Mallinckrodt. It is important to set the record straight.

Here are key facts:

- H.P. Acthar Gel is U.S. Food and Drug Administration (FDA)-approved for 19 indications, including for the treatment of Infantile Spasms, following a full label review by the Agency in 2010.
- The price of H.P. Acthar Gel today is $38,892, before discounts provided to payers. Since acquiring the drug in late 2014, Mallinckrodt has only made modest price adjustments in the mid-single digit percentage range.
- In contrast to the drug's prior owner Mallinckrodt has invested nearly $400 million into H.P. Acthar Gel, including investment into health economic and outcomes research and well-controlled clinical trials. Information on our total investment in H.P. Acthar Gel is publicly available on our website.
- Synacthen® (tetracosactide) is not H.P. Acthar Gel, nor is it an approved substitute for H.P. Acthar Gel in any of its indications in the U.S. Once we acquired the prior owner of Synacthen, we began developing the drug and in 2016, prior to the U.S. Federal Trade Commission (FTC) settlement, initiated clinical trials investigating use of the compound in Duchenne Muscular Dystrophy.
- Mallinckrodt strongly disagrees with the allegations contained in the City of Rockford, Illinois complaint.
- Mallinckrodt adheres to all regulations, guidance and codes related to interactions with healthcare providers.

Please see additional facts below along with other resources.

Patient Videos **Acthar.com** **Acthar Fact Sheet**



Clinical Presentation May 2017

June 29, 2018

The Facts About H.P. Acthar Gel

H.P. Acthar Gel (repository corticotropin injection) is for many frequently, very sick patients, a life-changing drug. We are proud of H.P. Acthar Gel and the important investment we are making in it, and we are gratified that we can positively impact patients' lives through this drug.

H.P. Acthar Gel is FDA-Approved for 19 Indications

While H.P. Acthar Gel has been used to treat patients for more than 50 years, its label was reviewed by the FDA in 2010, at which time the FDA determined there was sufficient scientific and clinical evidence to support its use in the 19 various indications1 contained in the current H.P. Acthar Gel label.

One of these indications is for use of **H.P. Acthar Gel in the treatment of Infantile Spasms (IS)2,** for which it is considered the gold-standard for treatment. Two randomized clinical trials were submitted in support of FDA approval of the drug and its effectiveness as a treatment for IS, one of which compared H.P. Acthar Gel to prednisone. In that trial 86.7% of patients had a positive response to H.P. Acthar Gel vs. 28.6% that responded to prednisone. Patients who responded in the pivotal study treated with a two-week course of H.P. Acthar Gel therapy experienced complete suppression of the two key measures of disease – spasms and hypsarrhythmia. The IS clinical trial results appear in Section 14 of the full prescribing information for the drug.

Aside from treatment of IS, H.P. Acthar Gel is often prescribed by doctors predominantly as a later-line treatment to a small subset of patients suffering from various devastating diseases for whom other approved FDA treatment options have failed.

The Price of H.P. Acthar Gel

In 2007, H.P. Acthar Gel's previous owner was near bankruptcy and raised the price of the drug substantially in order to keep the drug on the market and to ensure the long-term supply of the drug for treatment of children afflicted with infantile spasms and other small groups of patients suffering from complex, devastating diseases. They did this only after extensive consultation with the FDA.[3]

Today the price per vial of H.P. Acthar Gel is $38,892. Since acquiring H.P. Acthar Gel, Mallinckrodt has only made modest price adjustments in the mid-single digit percentage range. Additionally, Mallinckrodt provides discounts to this list price to payers, which the prior owner generally did not offer. We would encourage you to review Mallinckrodt's pledge on drug pricing and innovation, which we take very seriously.

NEW: Availability of H.P. Acthar Gel for Infantile Spasms Patients

- Mallinckrodt is committed to ensuring that any infant under the age of 2 suffering from infantile spasms (IS) who is prescribed H.P. Acthar® Gel receives treatment.[4]

- H.P. Acthar Gel samples are provided at no charge to physicians so they can provide the drug immediately upon diagnosis and assess the patient's clinical response to Acthar.
- All IS patient prescriptions received at the Acthar Hub are serviced urgently and with the utmost care knowing that a baby's well-being is at stake.
- A dedicated Acthar Hub Case Manager begins working immediately with the local Access and Reimbursement Manager to obtain insurance coverage and put the caregivers in touch with the Specialty Pharmacy to schedule expedited delivery.
- Mallinckrodt has a commercial copay assistance program to help offset out-of-pocket costs for eligible IS patients with no government insurance. The program offers a $0 co-pay for eligible patients.
    - Eligibility is established when the IS patient is a permanent U.S. resident, has a legal representative who is at least 18 years old, has been prescribed Acthar for this approved indication, and is commercially or privately insured.
    - The $0 co-pay program is not available to people insured by a federal or state healthcare plan or where prohibited by law.
- For those cases where the commercial or public insurance plan will not approve coverage for Acthar or the baby does not have insurance coverage – or for Medicaid patients whose families cannot afford the out-of-pocket costs – Mallinckrodt may provide Acthar at no cost to eligible patients through the Acthar Patient Assistance Program.
- Mallinckrodt also offers injection training services at no cost to the patient caregiver(s). A trained nurse will come to the best location (at the hospital, in the home, etc.) for the caregiver(s) and instruct them how to administer Acthar.

In short, Mallinckrodt invests significant resources to provide Acthar to babies quickly and with the utmost urgency. There is an entire support team that passionately and personally ushers each baby's prescription through the process to ensure no delays.

Mallinckrodt's Investment in H.P. Acthar Gel

Since acquiring H.P. Acthar Gel in 2014, Mallinckrodt has invested nearly $400 million into the drug, specifically: building on substantial clinical experience as well as previously completed and largely independent clinical case series and smaller trials; modernizing manufacturing; expanding medical affairs and research activities; and initiating six well-designed, company-sponsored randomized, controlled clinical studies, targeting combined enrollment of nearly 1,100 patients.3

Significant Clinical Evidence Supports the Efficacy of H.P. Acthar Gel

There is significant clinical evidence to support the effectiveness of H.P. Acthar Gel. This evidence is the result of company-sponsored controlled clinical trials, investigator-initiated research conducted in top hospitals and medical centers by some of the country's preeminent physicians, and health economic and outcomes research data. Equally important, there are decades of clinical experience that doctors have with the product as a proven therapy for appropriate patients.

As an FDA-approved drug, H.P. Acthar Gel is deemed safe and effective for its labeled indications by the agency. Since acquiring H.P. Acthar Gel, Mallinckrodt has, though, continued to conduct post-approval clinical studies in a number of key indications. Along with the wealth of clinical experience gained over the decades with this drug, this data will assist physicians in the use of H.P. Acthar Gel in the most appropriate patient populations.

NEW: Mallinckrodt recently published preliminary interim results of its Rheumatoid Arthritis Phase 4 Clinical Study for H.P. Acthar Gel. Details can be found here. The company also reported it achieved and exceeded enrollment for the trial.

NEW: Physician Payments/Travel Expense Reimbursement:

In the period of 2013-2016, of all healthcare practitioners prescribing H.P. Acthar Gel to whom Mallinckrodt or the prior owner made payments, **more than 95% received only modest meals or nominally priced clinical reprints** – well within regulations and guidelines. For the remaining ~5%, the vast majority were engaged for peer-to-peer speaking engagements, with a small fraction involved in other consulting services for the company, such as speaking to employees or investors and participation in expert Physician Advisory Boards – again, all within regulations and guidelines. It is our belief that many physicians prefer peer-to-peer presentations and dialogue over other methods of learning about the value a product may bring to appropriate patients they are treating. The physicians who present to their peers must take time away from their practice and frequently travel to other cities – incurring normal, but sometimes substantial travel expenses. Any payments reported include reimbursement for these expenses.

Mallinckrodt designs our policies to be consistent with applicable legal and regulatory requirements, the PhRMA Code, and industry best practices. We have instituted controls and strict guidelines regarding the selection and training of speakers; the conduct of such programs, including requirements related to the individuals that may attend such programs; and guidelines to ensure that the venues selected for such programs are appropriate and conducive to the educational focus of these programs, and payments are based on fair market value.

NEW: Adverse Events:

As an FDA-approved drug, H.P. Acthar Gel is deemed safe and effective for its labeled indications by the agency.

Mallinckrodt annually provides the FDA with data about adverse events related to its marketed products. As we approach our yearly filing, we are pleased to report that the positive benefit-risk of H.P. Acthar Gel has remained unchanged across all marketed indications and is consistent with previous years. To derive meaningful conclusions of this topic, adverse event reports for H.P. Acthar Gel need to be considered within the appropriate context.

H.P. Acthar Gel is typically prescribed to patients with very serious medical conditions, often as a third or fourth line of treatment when other treatments have failed. It is well known that many of these patients suffer from diseases in which co-morbidities are high, and often they are on other medications that may be contributing factors. The frequency of adverse event reports also does not necessarily correlate to an increase in the actual prevalence or relative severity of any particular side effect or event. Each event is reported and counted whether it relates to a relatively minor event such as a headache or a more serious event such as anaphylaxis.

Furthermore, the FDA itself cautions on its website that reporting of a side effect or adverse event occurring while taking a drug doesn't establish a causal relationship between the adverse event and the medicine.

Over the past years, the number of patients using H.P. Acthar Gel has increased significantly. Critically, however, company-generated H.P. Acthar Gel data on adverse events over the last four calendar years indicates that the number of serious adverse events as a proportion of the number of H.P. Acthar Gel prescriptions (measured by vials sold) has remained very low and consistent with the FDA's independent analysis.

NEW: H.P. Acthar Gel Advisory Committee Results

Regarding your questions on this topic, these are the facts: On May 11, 2010, a meeting of the FDA's Peripheral and Central Nervous System Drugs Division held an Advisory Committee Meeting (AdCom) to review/discuss the data Questcor was submitting/had submitted in support of use of H.P. Acthar Gel in treatment of patients with Infantile Spasms. The Committee voted 22 to 1 that H.P. Acthar Gel was an effective treatment for patients with IS and voted 20 to 1 the drug was safe in the intended patient population at an effective dosing regimen, inclusive of a Risk Evaluation and Mitigation Strategy (REMS). The REMS was a part of the agency's eventual approval of the drug for this indication (along with the reaffirmation of 18 others) in 2010. Two years later, the FDA removed the REMS requirement based on H.P. Acthar Gel's demonstrated safety in the market in IS patients.

The Facts about the Rockford Lawsuit

Mallinckrodt strongly believes that none of the company actions outlined in the plaintiff's complaint constitute a violation of any law and, therefore, believes that the complaint should be dismissed in its entirety. We will vigorously defend the company in this matter.

Treating physicians prescribe what they believe is best for their patients and the doctor(s) in Rockford, Illinois chose to prescribe H.P. Acthar Gel. The medical community is well aware that there are other treatment options for IS such as high dose steroids.

Synacthen, H.P. Acthar Gel and the FTC Settlement

Synacthen **is not a generic competitor** to H.P. Acthar Gel. While the two drugs may share mechanistic effects through the ACTH component, H.P. Acthar Gel is much more. H.P. Acthar Gel is a biologically derived corticotropin drug – not a steroid – and amongst its many components includes a 1-39 peptide chain, meaning it includes more than simply ACTH. Synacthen is a synthetic ACTH 24-peptide chain. The two products are very different drugs.

Mallinckrodt did not pursue commercialization of Synacthen for IS, as the barriers to completion were, in our view, virtually impossible to overcome.

- Synacthen has never been approved by the FDA for use in the U.S. for any indication and it is not an alternative treatment for IS in the U.S.
- In all the time that Synacthen has been commercially available in select foreign countries, it has never been commercialized in the U.S. and no owner of Synacthen (including the owner prior to Questcor) ever undertook U.S. development of the drug in IS or any other indication.
- Even in Canada, where Synacthen is approved and used in certain indications, it is not approved for use in IS patients. In fact, in Canada, the label contains a warning against use in infants or children under 3 years old due to the product containing benzyl alcohol.

Mallinckrodt is developing the drug (MNK-1411) in an indication where there is both high unmet medical need and, if successful, potential for greatest impact for patients – Duchenne Muscular Dystrophy.

Thank you for taking the time to read this important information.

1The FDA conducted a thorough review of the label for H.P. Acthar Gel in 2010.
2Because symptoms of IS can be subtle and are generally not widely recognized, Mallinckrodt invests resources to support education of the medical and patient community to ensure IS babies are getting diagnosed promptly. We also invest in ongoing clinical research to further understand the disease and since treating infantile spasms is so urgent once diagnosed Mallinckrodt has established an entire support team to usher each baby's prescription through the coverage process to ensure quick access to the product.
[3]Please see the Questcor's 10-K filing for 2007. Additionally, Questcor issued many new shares the year before, presumably to raise capital. Moreover, articles have appeared, including one in Investor's Business Daily in November of 2013 in which the former CEO of Questcor publicly discussed the company's challenges to stay afloat during this time period.
[4]Patients who withdrew from the process on their own would be exceptions to this statement.
[5]The six ongoing clinical trials are referenced below. Each link takes you to the announcement of the first patient enrolled in the clinical trial. Within each press release, in the "About the Trial" section, you will see a link to further details about the study that can be found on www.clinicaltrials.gov. These important investments will build upon the existing body of clinical evidence to support the effectiveness of H.P. Acthar Gel.

• Phase 2B trial in Amyotrophic Lateral Sclerosis
• Phase 4 trial in Pulmonary Sarcoidosis
• Phase 4 trial in Multiple Sclerosis Relapse
• Phase 4 trial in Lupus
• Phase 4 trial in Rheumatoid Arthritis
• Phase 4 trial in Focal Segmental Glomerulosclerosis (Nephrotic Syndrome)

About H.P. Acthar Gel (repository corticotropin injection)

INDICATIONS

H.P. Acthar Gel is an injectable drug approved by the FDA for the treatment of 19 indications. Of these, today the majority of Acthar use is in these indications:

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- The treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis)
- The treatment of symptomatic sarcoidosis
- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
- Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation

IMPORTANT SAFETY INFORMATION

Contraindications

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origins

Warnings and Precautions

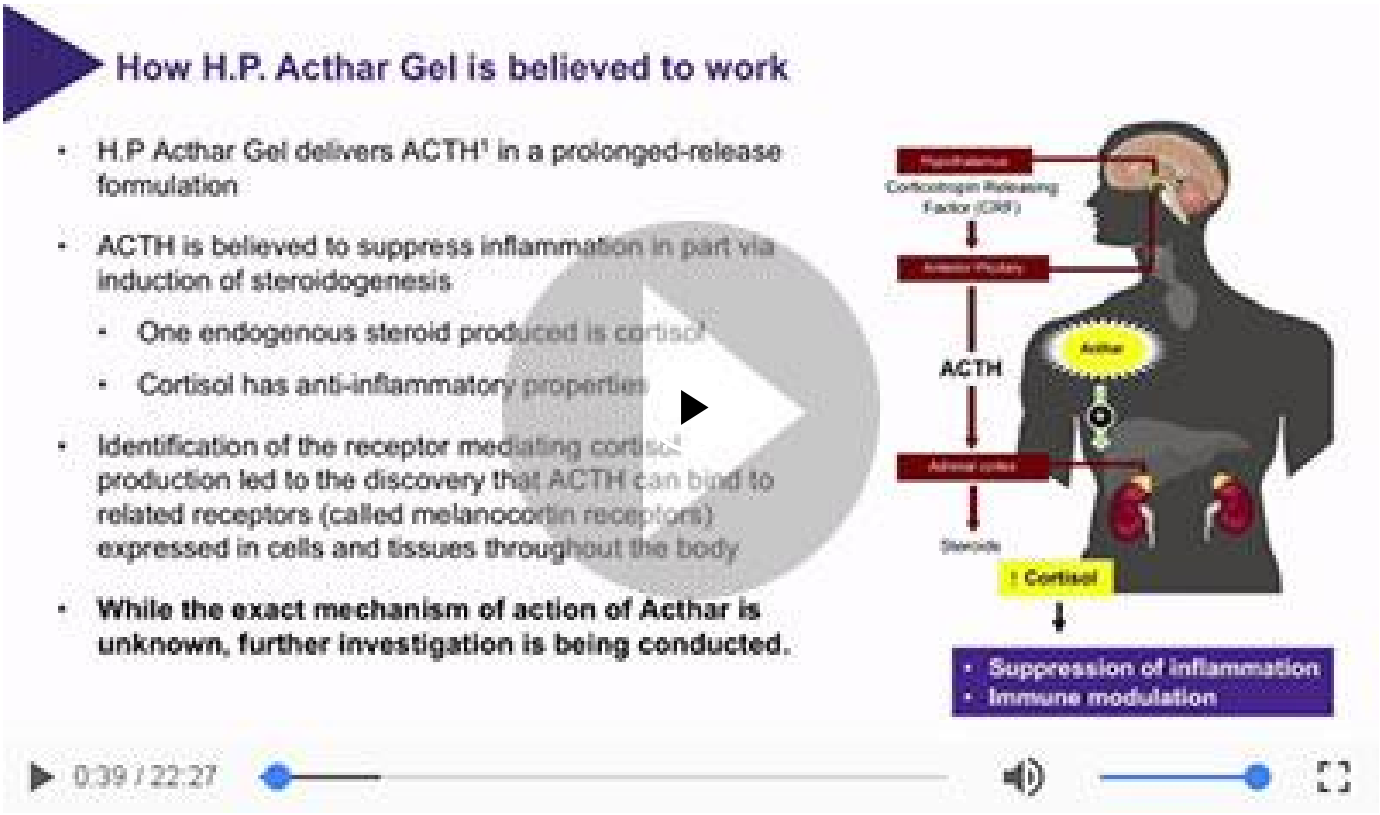
- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-axis (HPA) may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA suppression after stopping treatment
- Cushing's syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Blood pressure, sodium and potassium levels may need to be monitored
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression, and psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity
- There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Adverse Reactions

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash,

and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve

Other adverse events reported are included in the full Prescribing Information.
Please see full Prescribing Information available at Acthar.com.



Patient Videos

Each of the stories below provide a view of patients who are taking action to treat their disease or condition with Acthar.

Bella – infantile spasms
Christine – multiple sclerosis
Cynthia – dermatomyositis
Ella – infantile spasms
Daryl – multiple sclerosis
Gloria – rheumatoid arthritis
Kimberly – multiple sclerosis
Maby – multiple sclerosis
Tottie – polymyositis
Yosafa – multiple sclerosis
Zachary – infantile spasms

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, the States of ALASKA, MARYLAND, NEW YORK, TEXAS, and WASHINGTON, Plaintiffs, v. MALLINCKRODT ARD INC., formerly known as QUESTCOR PHARMACEUTICALS, INC., a California corporation, and MALLINCKRODT PLC, an Irish public limited company, Defendants.	Case Number:

COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiffs, the Federal Trade Commission ("FTC") and the states of Alaska, Maryland, New York, Texas, and Washington (collectively, the "Plaintiff States"), by their designated attorneys, petition this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, and the relevant state laws—Alaska Stat. §§ 45.50.501, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080—for permanent injunctive and other equitable relief against Defendants Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc. ("Questcor"), and Mallinckrodt plc ("Mallinckrodt") to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and acts of monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and various state laws as identified in Count III, and state for their complaint as follows:

I. Nature of the Case

1. Through its anticompetitive conduct, Questcor has extinguished a nascent competitive threat to its monopoly. Questcor's H.P. Acthar Gel ("Acthar") is the only therapeutic adrenocorticotropic hormone ("ACTH") product sold in the United States. ACTH is the standard of care for infantile spasms ("IS"), a rare but extremely serious disorder involving seizures within the first two years of life. It is also used to treat nephrotic syndrome ("NS")—a kidney disorder whose largest single cause is idiopathic membranous nephropathy ("IMN")—as well as other disorders.

2. Questcor acquired Acthar from Aventis Pharmaceuticals, Inc. in 2001 for $100,000 plus modest royalties. At that time, the price of Acthar was $40 per vial. Questcor has since raised Acthar's price to over $34,000 per vial—an 85,000% increase.

3. A course of Acthar treatment for IS requires multiple vials and can cost well over $100,000.

4. For other indications, as the CEO of Mallinckrodt has admitted, Acthar is in many cases "the only alternative for patients that have tried and failed on many other therapies."

5. Questcor's Acthar price increases have persisted and proved very profitable. Acthar's U.S. revenues in 2015 exceeded $1 billion.

6. In Europe, Canada, and other parts of the world, doctors treat patients suffering from these same conditions with Synacthen Depot ("Synacthen"), a synthetic ACTH drug. Although Acthar is a natural ACTH drug derived from the pituitary glands of pigs, Acthar and Synacthen have very similar biological activities and pharmacological effects. As the Canadian product monograph for Synacthen reads, "SYNACTHEN . . . exhibits the same activity as natural ACTH with regard to all its biological activities." Questcor considers the drugs so

similar that it submitted Synacthen information to support its application to the U.S. Food and Drug Administration ("FDA") to expand the label indications for Acthar and cited Synacthen studies in its Acthar marketing materials.

7. Until June 2013, Novartis AG ("Novartis") marketed and sold Synacthen abroad.

8. In 2011, Novartis decided to sell the rights to market Synacthen in the United States. For years, Questcor had viewed Synacthen as a significant potential competitive threat to Acthar. In June 2013, Questcor outbid other companies to acquire the U.S. rights to Synacthen. Questcor's participation in the bidding process was a defensive move designed to protect its monopoly over ACTH drugs in the United States. By acquiring Synacthen, Questcor harmed competition by preventing another bidder from trying to develop the drug and launch it in the United States to challenge Questcor's monopoly over ACTH drugs.

II. The Parties

9. Plaintiff FTC is an administrative agency of the United States, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 et seq., with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC is vested with the authority and responsibility for enforcing, inter alia, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to seek injunctive relief to prevent or remedy violations of any law the FTC enforces and to seek equitable remedies.

10. The Attorneys General of the Plaintiff States are the chief legal officers for their respective states. They are granted authority under federal antitrust law to bring actions for injunctive relief and under the laws of their respective states to bring actions to ensure compliance with their state laws and to enjoin violations of state law.

11. Defendant Mallinckrodt is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

12. Mallinckrodt acquired Questcor on August 14, 2014, for approximately $5.9 billion. At that time, Acthar was the only drug product sold by Questcor. With Mallinckrodt's acquisition, Questcor became a wholly owned subsidiary of Mallinckrodt and subsequently changed its corporate name from Questcor Pharmaceuticals, Inc. to Mallinckrodt ARD Inc.

13. Defendant Mallinckrodt ARD Inc. is a biopharmaceutical company incorporated in California and headquartered in Anaheim, California. The company manufactures and sells Acthar in the United States.

III. Jurisdiction and Venue

14. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

15. This Court has personal jurisdiction over Defendants pursuant to 15 U.S.C. § 53(b) because each Defendant has the requisite constitutional contacts with the United States of America.

16. In conjunction with the Commission, the Plaintiff States also bring this action for civil penalties and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501, 45.50.551, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080. All claims under federal and state law are based upon a common nucleus of operative fact, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction over the non-federal claims under 28 U.S.C. § 1367(a), as well as

under principles of pendent jurisdiction.

17. Venue in this district is proper under Section 13(b)(2) of the FTC Act, 15 U.S.C. § 53(b), 15 U.S.C. § 22, and 28 U.S.C. § 1391(b), (c), and (d). Each Defendant resides, transacts business, or is found in this district.

18. Questcor and Mallinckrodt are, and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12. Defendants also are, and at all relevant times have been, engaged in commerce in each of the Plaintiff States.

19. Questcor and Mallinckrodt are, and at all times relevant have been, a "corporation," as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

IV. Questcor Possesses Monopoly Power With Acthar

20. Questcor has exercised, and continues to exercise, monopoly power in the United States with Acthar. The supracompetitive prices that Questcor charges for Acthar and its restriction of Acthar's output are direct evidence of this monopoly power. Questcor's monopoly power is also established by indirect evidence, which shows that Acthar holds a dominant share of the relevant market for ACTH drugs in the United States. That market is and has been characterized by substantial barriers to entry.

A. Direct Evidence of Acthar's Monopoly Power

21. Questcor has repeatedly and profitably raised Acthar's price substantially over the last decade. On August 27, 2007, Questcor increased the price of Acthar more than 1,300% overnight, from $1,650 to $23,269 per vial, causing its revenues to increase dramatically and its profits to soar. Additionally, Questcor has taken significant and profitable increases on eight occasions since 2011, pushing the price up another 46% to its current $34,034 per vial. Acthar

net sales grew from $218 million in 2011 to more than $1 billion in 2015.

22. Each alternative bidder expected to profitably sell Synacthen at a price well below Acthar's price, demonstrating that Acthar is currently priced at a supracompetitive level. The lower prices that would prevail in a duopoly market containing Acthar and Synacthen show that Acthar is currently extracting substantial monopoly rents.

23. Questcor restricts the output of Acthar by charging an extraordinarily high price, forcing third-party payers (e.g., health insurers) to limit Acthar's usage to the narrowest possible group of patients—those for whom no effective therapeutic alternatives exist. When Questcor implemented its 1,300% price increase in 2007, payers implemented formulary restrictions on Acthar. Most payers continue to impose stringent restrictions on Acthar. By setting a supracompetitive price and restricting the output of Acthar, Questcor has reduced market-wide output below competitive levels.

B. Indirect Evidence of Acthar's Monopoly Power

24. The relevant product market is ACTH drugs.

25. Questcor has encountered no competitive constraint on its ability to repeatedly and profitably increase Acthar's price and earn extremely high margins. Questcor does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications.

26. Acthar is indicated for the treatment of IS. Pediatric neurologists consider ACTH the gold standard treatment for IS. Other market participants—including doctors, third-party payers, and pharmaceutical companies (including Questcor)—agree. Treating an infant with IS using Acthar can cost more than $100,000. The only other treatment that is FDA-approved for

IS is Sabril, which has a completely different molecular structure and mechanism of action than Acthar and is used primarily in a discrete subset of IS patients. At approximately $25,000 per course of treatment, Sabril costs substantially less than Acthar. Although some doctors prescribe other treatments for a minority of IS patients, those treatments work differently than Acthar and are not substitutes for Acthar. Neither the price of Sabril nor the prices of other IS treatments have affected Acthar's pricing, and none of these other treatments constrains the price of Acthar.

27. Acthar is indicated for the treatment of IMN. Because of its high price, Acthar typically is prescribed only as a last-line therapy to treat IMN. A course of Acthar treatment for IMN can cost hundreds of thousands of dollars. Nephrologists prescribe low-cost, generic oncology agents or immunosuppressants as first and second-line therapies to treat most IMN patients. If those therapies fail or cannot be tolerated, some doctors may prescribe the drug Rituxan, whose costs can range from approximately $13,000 to $40,000 for a course of treatment. Because Acthar functions differently than any of these other therapies, doctors and payers do not consider these therapies substitutes for Acthar, and the price of Acthar is not constrained by any of these treatments.

28. Acthar is indicated for the treatment of other indications, including MS flare-ups and rheumatology conditions. For these indications, the price of Acthar is unconstrained by other drugs used to treat those conditions.

29. Even if Synacthen were approved by the FDA for only one of Acthar's indications, Synacthen would compete directly with Acthar and would be properly included in the relevant market. Synacthen is pharmacologically very similar to Acthar, as the active ingredient in both drugs is an ACTH molecule. Many doctors would prescribe Synacthen as a substitute for Acthar, and many payers would require its use in place of Acthar. Each alternative

purchaser of the Synacthen assets expected to compete head-to-head with Acthar and to take a substantial amount of Acthar's business with both on- and off-label sales.

30. The relevant geographic market is the United States. FDA approval is required to market pharmaceuticals to U.S. consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for U.S. consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

31. Acthar has a 100% share of the market for ACTH drugs in the United States. No other ACTH drug is FDA-approved for therapeutic use.

32. The U.S. ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's CEO has assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

V. Questcor Engaged in Anticompetitive Conduct By Acquiring Synacthen

33. Synacthen posed a threat to Questcor's ACTH drug monopoly, so Questcor intervened when other firms attempted to acquire the U.S. rights to Synacthen from Novartis. Questcor submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Questcor eliminated the possibility that another firm would develop it and compete against Acthar.

A. Synacthen Posed a Nascent Competitive Threat to Acthar

34. Synacthen constituted a nascent competitive threat to Questcor's ACTH drug monopoly, notwithstanding the significant uncertainty that Synacthen, a preclinical drug, would be approved by the FDA.

35. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly.

36. In 2006, when Questcor decided to pursue an "orphan" (i.e., high) pricing model for Acthar, it recognized the potential threat Synacthen posed to Acthar's revenue growth.

37. In 2009, Questcor approached Novartis about acquiring Synacthen. At that time, Questcor continued to view Synacthen as a possible future competitor. Unsuccessful in that attempt, Questcor continued to monitor the competitive threat from Synacthen.

38. In 2012, Questcor again concluded that Synacthen posed a threat to Acthar should it be approved for sale in the United States.

39. In 2013, Questcor feared that if another company were to acquire Synacthen and obtain FDA approval, it could decimate its business.

40. But as long as Questcor believed no other firm was seeking to bring Synacthen to the United States, Questcor did not make further attempts to acquire it. Just months before Questcor began pursuing the acquisition of Synacthen, top Questcor officials questioned whether Synacthen would provide any affirmative value to Questcor.

B. Other Bidders Planned to Use Synacthen to Challenge Acthar's Monopoly

41. Unbeknownst to Questcor at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug

was already approved and sold. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

42. Each of the three firms planned to develop Synacthen for IS and/or IMN and use Synacthen to compete directly with Acthar. With approval for one or both of these indications, each firm expected to capture a significant share of the U.S. ACTH market from Questcor by pricing Synacthen well below Acthar. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the U.S. market.

C. The Value of the Synacthen Assets

43. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation has been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

44. The asset package sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

45. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation de novo, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

D. Questcor Disrupted the Synacthen Bidding Process

46. In October 2012, Questcor learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis and develop it for the United States. Questcor immediately attempted to reach Novartis and shortly thereafter signed a confidentiality agreement with Novartis and submitted an offer for Synacthen.

47. Novartis negotiated with the three alternative bidders in parallel with Questcor. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company had exchanged deal terms with Novartis and had submitted a formal offer. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on U.S. Synacthen sales.

48. Unlike the three alternative bidders, Questcor had only inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis.

49. On June 11, 2013, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"), pursuant to which Questcor gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Questcor is obligated to pay a minimum of $135 million, and likely will pay $300 million to Novartis for Synacthen.

E. Questcor's Acquisition of Synacthen Harmed Competition

50. Questcor's strategy to protect its monopoly position with Acthar was successful. But for Questcor's acquisition of Synacthen, one of the three alternative bidders would have acquired Synacthen and pursued its plan to develop Synacthen for IS and/or IMN to compete

directly with Acthar at a lower price. With the acquisition of Synacthen, Questcor thwarted a nascent challenge to its Acthar monopoly and thereby harmed competition.

51. Questcor claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the drugs' similarities, any therapeutic indication that Questcor pursues with Synacthen could have been pursued with Acthar.

52. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for $5.9 billion. The vast majority of Questcor's value was attributable to Acthar.

COUNT I – Monopolization in Violation of the FTC Act

53. Plaintiff the FTC re-alleges and incorporates by reference all of the allegations in the above paragraphs.

54. Defendants have, and at all relevant times had, monopoly power in the market for the sale of ACTH drugs in the United States.

55. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

56. Defendants' acts and practices are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT II – Monopolization in Violation of the Sherman Act

57. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

58. Defendants have, and at all relevant times had, monopoly power in the market for

the sale of ACTH drugs in the United States.

59. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

60. Defendants' acts and practices constitute monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT III – Supplemental State Law Claims

61. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

62. The aforementioned practices by Defendants were and are in violation of Alaska's Restraint of Trade Act, Alaska Stat. §§ 45.50.562 et seq., Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. §§ 45.50.471 et seq., and the common law of Alaska.

63. The aforementioned practices by Defendants were and are in violation of the Maryland Antitrust Act, Md. Code Ann., Com. Law §§ 11-201 et seq.

64. The aforementioned practices by Defendants were and are in violation of New York's antitrust law, the Donnelly Act, New York Gen. Bus. Law §340 et seq., and is proscribed by New York Executive Law 63(12), in that the aforementioned practices constitute illegality and/or illegal acts in the carrying on, conducting, or transacting of business.

65. The aforementioned practices by Defendants were and are in violation of Texas's Free Enterprise and Antitrust Act, Tex. Bus. & Com. Code Ann. §§ 15.01 et seq.

66. The aforementioned practices by Defendants were and are in violation of Washington's Consumer Protection Act, Wash. Rev. Code §§ 19.86 et seq., as proscribed by §

19.86.040, in that the aforementioned practices are unlawful in any part of trade or commerce.

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501 and 45.50.580, Md. Code Ann. Com. Law § 11-209, New York Gen. Bus. Law §340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080 empower this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, Plaintiffs request that this Court enter final judgment against Defendants Mallinckrodt and Questcor:

1. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a),

2. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

3. Adjudging that Defendants have committed violations of each of the state laws enumerated in Count III;

4. Ordering that Defendants are permanently enjoined from engaging in similar and related conduct in the future;

5. Ordering divestiture and any further actions needed to restore competition lost due to the Defendants' violations;

6. Granting such other equitable relief as the Court finds necessary, including equitable monetary relief, to redress and prevent recurrence of Defendants' violations of Section 5(a) of the FTC Act, Section 2 of the Sherman Act, and the state laws enumerated in Count III,

as alleged herein;

7. Ordering Defendants to pay civil penalties pursuant to Alaska Stat. §§ 45.50.551(b) and 45.50.578(b)(2), Md. Code Ann., Com. Law § 11-209(a)(4), New York Gen. Bus. Law §342-a, Tex. Bus. & Com. Code Ann. §15.20(a), and Rev. Code of Wash. Ann. § 19.86.140; and

8. Awarding the Plaintiff States the costs of this action, including reasonable attorneys' fees and costs, as provided for in the Clayton Act and applicable state law.

Dated: January 18, 2017

Respectfully Submitted,

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FILED

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

RETROPHIN, INC., a Delaware Corporation,

Plaintiff,

vs.

QUESTCOR PHARMACEUTICALS, INC., a California Corporation,

Defendant.

SA CV14-00026-JLS (JPRx)

COMPLAINT FOR:

1. **RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. § 1 ET SEQ.)**
2. **MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2 ET SEQ.)**
3. **ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2 ET SEQ.)**
4. **UNLAWFUL MERGER IN VIOLATION OF SECTION 7 OF THE CLAYTON ACT (15 U.S.C. § 18 ET SEQ.)**
5. **VIOLATION OF CALIFORNIA ANTITRUST LAWS**
6. **VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAWS**

DEMAND FOR JURY TRIAL

PAID
JAN - 7 2014
Clerk, U.S. District Court

Plaintiff Retrophin, Inc. ("Retrophin"), as and for its complaint against Defendant Questcor Pharmaceuticals, Inc. ("Questcor"), alleges as follows:

Nature of the Action

1. Questcor is a monopolist. It is the sole provider in the US of approved therapeutic preparations of adrenocorticotropic hormone ("ACTH"), a drug used to treat certain life threatening and often fatal diseases. Questcor's ACTH drug is sold under the brand name H.P. Acthar Gel ("Acthar"). The drug is not patented.

2. Questcor acquired the rights to Acthar in 2001. At the time, Acthar sold for $50 a vial or less. Since then, Questcor has raised the price to $28,000 – a 56,000% price increase.

3. Questcor is able to charge such an extortionate price for Acthar because it holds a monopoly in the US. Its monopoly exists for several reasons. First, Acthar is the only long acting ACTH therapeutic drug approved by the Food and Drug Administration ("FDA") for use in the US. Second, Acthar is the most effective and dominant first line treatment for Infantile Spasms, an often fatal disorder that causes epileptic type seizures in babies, toddlers and children under the age of 5. In addition, Questcor has obtained "Orphan Drug Designation" for Acthar from the FDA under the Orphan Drug Act, 21 USC §§301 *et seq.*, giving it the exclusive right to market Acthar – and its chemical equivalent – for use in treating Infantile Spasms. Third, Acthar is also the most commonly used treatment of last resort for patients suffering from Nephrotic Syndrome, a condition that results in excessive protein being secreted through the urine that destroys the kidneys and can lead to kidney failure. Treatments of last resort, as the term implies, are used for patients who do not respond to or cannot tolerate other therapies used to treat their illness.

4. In June of 2013, plaintiff Retrophin was poised to challenge Questcor's monopoly. It had negotiated an agreement to purchase from Novartis AG ("Novartis"), the rights to sell in the US a product called Synacthen, an ACTH drug that contains the same sequence of the first 24 amino acids that is found in Acthar.

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While there are differences between Acthar and Synacthen – the two are not chemically identical beyond the first 24 amino acids and they are produced differently – Synacthen has been sold for years outside of the US for the treatment of Infantile Spasms, Nephrotic Syndrome, Multiple Sclerosis and other diseases. On information and belief, it is not currently sold in the US because it has never been submitted to the FDA for approval.

5. Retrophin planned to obtain FDA approval to sell Synacthen in the US and compete head to head against Questor by dramatically undercutting Questcor's price for Acthar. It had negotiated and was ready to sign an agreement to purchase the US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013. The signing of the agreement was so imminent that a press release had been prepared to announce the deal.

6. On June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor swept in and acquired the rights to Synacthen. In so doing, it preserved and entrenched its ACTH monopoly in the US and eliminated the competitive threat posed by Retrophin's acquisition of Synacthen. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

7. When it acquired the rights to Acthar, Questcor did not make a Premerger Notification Filing with the Department of Justice and the Federal Trade Commission under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 USC, §18a *et seq.*

8. Questcor was quite aware, however, that its agreement with Novartis raised serious antitrust questions. The agreement provides that, if Questcor is forced to divest its rights to Synacthen on antitrust grounds, Novartis will keep the entire $60 million that Questcor had paid it. In addition, Questcor remains obligated to make all future milestone payments owed to Novartis under that agreement – an amount in excess of $75 million. Questcor has accepted the entire economic risk – an amount in

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excess of $135 million – that the agreement with Novartis would be deemed illegal under the antitrust laws.

9. Questcor's acquisition of Synacthen has delayed, and may completely foreclose, Retrophin's entry into the markets defined below. It will delay, and may completely prevent, Retrophin from competing against Questcor. Retrophin brings this lawsuit to recover the damages it has incurred as a result of Questcor's anticompetitive and monopolistic conduct. It also seeks injunctive relief against Questcor's continuation of such conduct.

The Parties

10. Plaintiff Retrophin is organized and exists under the laws of Delaware. Its principal place of business is located at 777 Third Avenue, 22nd Floor, New York, New York 10017. It also does business in California and Massachusetts.

11. Retrophin is a biopharmaceutical company focused on the development, acquisition and commercialization of drugs for the treatment of serious, catastrophic or rare diseases for which there are currently no viable options for patients. The diseases on which Retrophin focuses are often considered "orphan" diseases because they affect fewer than 200,000 patients in the United States. Retrophin has acquired and is building a pipeline of innovative product candidates for several catastrophic diseases, including: Focal Segmental Glomerulosclerosis, a kidney disease; Pantothenate Kinase-Associated Neurodgeneration; and Duchenne Muscular Dystrophy.

12. Defendant Questcor is a corporation organized and existing under the laws of the State of California. It maintains its principal place of business in Anaheim, California.

Jurisdiction and Venue

13. Retrophin brings this action under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15 and 26, to recover treble damages and costs of suit, including reasonable attorneys' fees, and for injunctive relief, for injuries suffered by Retrophin

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alleged herein and arising from Questcor's continuing violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 7 of the Clayton Act, 15 U.S.C. § 18. Jurisdiction for this action is invoked under Sections 4 and 16 of the Clayton Act, as amended, 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337(a).

14. Additionally, this Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because the controversy exceeds the sum or value of $75,000 and Retrophin and Questcor are citizens of different states. This Court has supplemental jurisdiction over Retrophin's state law claims pursuant to 28 U.S.C. § 1367(a).

15. Venue in this Court exists by virtue of Sections 4 and 12 of the Clayton Act, as amended, 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(c). Defendant Questcor is found, has agents, transacts and is doing business in this District, and the unlawful activities complained of herein were carried on, in substantial part, within this District.

16. Defendant is subject to personal jurisdiction in this Court because it resides in this District and transacts business in this District.

Trade and Commerce

17. The pharmaceutical products at issue in this case are sold in Interstate Commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had and will have, a substantial effect upon, Interstate Commerce.

The Relevant Markets

18. There are a number of separate relevant product markets at issue in this case. They include: (a) the market for ACTH therapeutic drugs (the "ACTH Therapeutic Drug Market"); (b) the market for first-line drug treatments for Infantile Spasms (the "Infantile Spasms Market"); and (c) the market for treatments of last resort for Nephrotic Syndrome for those patients who do not respond to or cannot tolerate primary and secondary treatments for that disease (the "Nephrotic Syndrome

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Market"). The relevant geographic markets for each of these three relevant product markets is the United States, since drugs available in any of these markets are subject to FDA regulation. The ACTH Therapeutic Drug, Infantile Spasms, and Nephrotic Syndrome Markets are collectively referred to as the "Relevant Markets."

The ACTH Therapeutic Drug Market

19. ACTH is a drug used to treat certain life threatening and often fatal diseases, including Infantile Spasms and Nephrotic Syndrome. It is a polypeptide tropic hormone produced and secreted by the anterior pituitary gland. In the human body, ACTH activates the Melanocortin System and is referred to as a "Melanocortin agonist." The Melanocortin System affects a wide array of bodily functions ranging from skin pigmentation, inflammation, energy homeostasis and sexual function. As a consequence, ACTH can be used as a therapy for a variety of illnesses resulting from improper functioning of the Melanocortin System, including Infantile Spasms and Nephrotic Syndrome. There is no reasonable interchangeability between drug therapies used to treat other diseases and ACTH drug therapies used to stimulate the Melanocortin System.

20. Acthar is an ACTH. It is the only FDA approved long-acting ACTH available in the US. It is also the only FDA approved long-acting melanocortin agonist available in the US.

21. ACTH products have been approved for use as diagnostic agents which are used to test for the presence of certain conditions or diseases. However, those products are short acting and are not used as therapies in treating illnesses.

22. Consumers faced with a small but significant non-transitory increase in the price of ACTH therapeutic drugs, cannot and will not shift to other classes of drugs such that the increase in price will be rendered unprofitable. This is evidenced by the fact that Questcor, the only supplier of ACTH for therapeutic purposes in the US, has raised the price of a vial of Acthar to $28,000 and is able to maintain that price.

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23. FDA regulation and the difficulty of developing and manufacturing ACTH based therapeutic drugs reduce or eliminate any "supply elasticity" whereby manufacturers of other drug therapies convert their existing manufacturing facilities to the manufacture of ACTH therapeutic drugs.

24. The relevant geographic market for ACTH therapeutic drugs is national because therapeutic ACTH drugs cannot be sold in the US without FDA approval.

The Infantile Spasms Market

25. Babies and little children suffering from Infantile Spasms must have treatments that cure that affliction. Without it they suffer from epileptic type seizures and other symptoms of the disease. If untreated, they may suffer permanent brain or neurological damage and may develop other seizure disorders. The disease can be fatal. Only therapies that treat Infantile Spasm Syndrome can meet the medical needs of these patients. Therapies for other diseases do not cure or control Infantile Spasms and are not substitutes for Infantile Spasm therapeutics. There is no reasonable interchangeability between drug therapies used to treat other diseases and drug therapies used to treat children with Infantile Spasms.

26. Consumers faced with a small but significant non-transitory increase in the price of therapeutic drugs to treat Infantile Spasms, cannot and will not shift to other drug treatments for Infantile Spasms such that the increase in price will be rendered unprofitable. This is evidenced by the fact that Questcor has raised the price of a vial of Acthar to $28,000 and is able to maintain that price.

27. There are also regulatory entry barriers that limit the Relevant Market to first line therapies for Infantile Spasms. In 2010, Questcor obtained from the FDA, "Orphan Drug designation" for Acthar for Infantile Spasms under the Orphan Drug Act. Despite the fact that Acthar is not patented, the Orphan Drug designation gives Questcor a seven year exclusive right to sell Acthar, and its chemical equivalent, for Infantile Spasms with immunity from generic competition. Questcor's exclusive marketing right extends to 2017. Therapies that are excluded by Acthar's Orphans

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Drug Designation (generic versions of Acthar) cannot be labeled or marketed for the treatment of Infantile Spasms.

28. FDA regulation and the difficulty of developing and manufacturing treatments for Infantile Spasms preclude any "supply elasticity" whereby manufacturers of other drug therapies convert their manufacturing facilities to the manufacture of Infantile Spasm therapies.

29. The relevant geographic market for first line Infantile Spasm drug therapies is national because therapeutic drugs cannot be marketed in the US for Infantile Spasms without FDA approval.

The Nephrotic Syndrome Market

30. Nephrotic Syndrome is a condition in which excessive amounts of protein pass through the kidneys and are secreted through the urine. This results in kidney damage and can lead to kidney failure. Nephrotic Syndrome is treated on a first and second line basis with corticosteroids, such as Prednisone, or immunosuppressant drugs. In some patients the disease does not respond to these treatments and in others the patient cannot tolerate the drugs' side effects. In such cases, ACTH (Acthar) is the primary and dominant treatment of last resort. Only therapies that treat Nephrotic Syndrome effectively can meet the medical needs of Nephrotic Syndrome patients who do not respond to or cannot tolerate traditional first and second line therapies for that illness. Therapies for other diseases do not cure or control Nephrotic Syndrome and are not substitutes for last resort treatments for Nephrotic Syndrome. There is no reasonable interchangeability between drug therapies used to treat other diseases and drug therapies used to treat victims of Nephrotic Syndrome.

31. Consumers faced with a small but significant non-transitory increase in the price of last resort therapeutic drugs to treat Nephrotic Syndrome cannot and will not shift to other drug treatments such that the increase in price will be rendered

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unprofitable. This is evidenced by the fact that Questcor has raised the price of a vial of Acthar to $28,000 and is able to maintain that price.

32. There are also regulatory entry barriers that limit the Relevant Market to therapies of last resort for Nephrotic Syndrome. Therapies for other conditions cannot be marketed for the treatment of Nephrotic Syndrome without FDA approval. In addition, it is particularly difficult for the maker of a generic drug to obtain FDA approval when it is trying to prove that its synthetically manufactured product, which is manufactured in a laboratory setting, is the biopharmaceutical equivalent of a drug such as Acthar which is produced from animals.

33. FDA regulation and the difficulty of developing and manufacturing treatments for Nephrotic Syndrome preclude any "supply elasticity" whereby manufacturers of other drug therapies convert their manufacturing facilities to the manufacture of Nephrotic Syndrome therapies.

34. The relevant geographic market for therapies of last resort for Nephrotic Syndrome is national because such therapies cannot be marketed in the US for Nephrotic Syndrome without FDA approval.

Questcor Has Market and Monopoly Power in the Relevant Markets

35. There are no meaningful substitutes for Acthar or ACTH in the Relevant Markets. Nor are manufacturers of other pharmaceutical products able to shift their production to the manufacture of Acthar or other ACTH products. Even if they were able to do so, they could not sell those products without first obtaining FDA approval. Questcor has market and monopoly power in all of the Relevant Markets.

36. Questcor's monopoly power in all three of the Relevant Markets is further evidenced by a single price increase that it imposed in 2007. In that year, Questcor raised the price of Acthar from $1,650 per vial to $23,000 per vial, an overnight increase of over 1,300%. Questcor's ability to make that price increase "stick" is conclusive evidence of its market and monopoly power.

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The ACTH Therapeutic Drug Market

37. In the ACTH Therapeutic Drug Market, Acthar is the only FDA approved long acting ACTH therapeutic drug available to consumers in the United States.

38. Questcor's market and monopoly power in the ACTH Therapeutic Drug Market is further protected by the fact that other chemical variations of ACTH for use as therapeutic drugs require FDA approval for sale in the United States.

39. Questcor effectively has 100% of the market for ACTH Therapeutic Drugs. It has market and monopoly power in that market which is dramatically demonstrated by its continued ability to charge $28,000 for a vial of Acthar.

The Infantile Spasms Market

40. In the Infantile Spasms Market, Acthar is considered the "gold standard" of treatment.

41. Questcor's market and monopoly power in the Infantile Spasms Market is protected by the Orphan Drug Designation that protects Questcor from generic competition to Acthar. Its monopoly position is further protected by the fact that alternative therapies, that would not be precluded by the Orphan Designation, require FDA approval if they are to be marketed as therapies for Infantile Spasms.

42. Questcor admits that it has more than 50% share of the Infantile Spasms Market and its actual market share may be far greater. Questcor's market and monopoly power in the Infantile Spasms Market is demonstrated dramatically by its continued ability to charge $28,000 for a vial of Acthar.

The Nephrotic Syndrome Market

43. In the Nephrotic Syndrome Market, Acthar is the primary and dominant treatment of last resort for Nephrotic Syndrome patients who do not respond to or cannot tolerate first or second line treatments for that disease.

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44. Questcor's market and monopoly power in the Nephrotic Syndrome Market is further protected by the fact that alternative drug therapies require FDA approval if they are to be marketed as therapies for Nephrotic Syndrome.

45. Questcor's market and monopoly power in the Nephrotic Syndrome Market is demonstrated dramatically by its continued ability to charge $28,000 for a vial of Acthar.

Retrophin's Acquisition of Synacthen Threatened Questcor's Monopoly

46. Synacthen is an ACTH derivative that has been sold for years outside of the US and has been used successfully to treat patients with Infantile Spasms and Nephrotic Syndrome in other countries. It has not been commercially developed in the US and it has not been submitted to the FDA for approval for therapeutic use.

47. Synacthen is similar, but not chemically identical, to Acthar. Both drugs share the identical sequence of the first 24 amino acids in their respective molecules. This sequence of amino acids gives both drugs their therapeutic properties. Acthar, however, has a longer amino acid chain. The two drugs are also produced in very different ways. Acthar is "porcine derived." It is extracted from the pituitary gland found in the brains of slaughtered pigs. Synacthen, by contrast, is synthetically manufactured in a laboratory setting. These differences give Synacthen three competitive advantages over Acthar. First, Synacthen is less expensive to manufacture. Second, because it is manufactured in a controlled setting, the product is less susceptible to variation. Third, consumers are more comfortable knowing that the drugs they are taking – or giving to their infants – are produced in a sterile environment rather than being derived from slaughtered animals.

48. Retrophin planned to purchase the rights to Synacthen, obtain FDA approval for its use as a therapeutic, and enter the Relevant Markets in competition with Questcor. Retrophin planned to price Synacthen at a fraction of the price charged by Questcor and use its competitive pricing and Synacthen's other competitive advantages to take substantial market share from Acthar.

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49. In the late summer of 2012, Retrophin entered negotiations with Novartis to purchase the rights to manufacture and sell Synacthen in the US. After approximately nine months of due diligence and negotiations, Retrophin and Novartis agreed to terms on which Retrophin would acquire the rights to Synacthen. Final documents had been prepared and were merely awaiting the parties' signatures. The signing was set for June 11, 2013. Retrophin had prepared a press release announcing the deal.

50. In anticipation of the transaction, Retrophin had prepared a plan to obtain regulatory approvals for, and sell Synacthen. It devised a strategy for going directly to Phase III clinical drug trials in order to obtain FDA approval for the use of Synacthen to treat Infantile Spasms and Nephrotic Syndrome. It also planned to file a Treatment Investigational New Drug Application which, if approved by the FDA, would have allowed Retrophin to offer Synacthen to patients for free while it was awaiting FDA approval to market Synacthen for Infantile Spasms and Nephrotic Syndrome. This would have given patients immediate relief from Questcor's pricing and would have developed substantial goodwill for Retrophin and Synacthen in both the patient and medical communities. Retrophin believed that the history of Synacthen's use in other countries would aid it in obtaining FDA approval.

51. In anticipation of the product launch, Retrophin had put in place a clinical apparatus to conduct clinical trials necessary to obtain FDA approval. It planned to begin to market Synacthen upon FDA approval.

52. Given its expertise as a biopharmaceutical company focusing on rare diseases, Retrophin was ready, willing and able to enter the Relevant Markets with Synacthen subject to FDA approval. Retrophin's entry into the Relevant Markets would have broken Questcor's monopoly. The result would have been unambiguously procompetitive. Retrophin's entry into the market and its introduction of Synacthen as an alternative to Acthar would have benefitted all participants in the markets – other than Questcor. Prices to patients and payors would have dropped;

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patients who were unable to pay for the drug would have been able to get it; other patients who were forced by Questcor's pricing to limit their dosages of the drug would have been able to take the medically prescribed amounts; and Retrophin would have earned substantial profits from sales of its product.

Questcor Illegally Acquires Synacthen to Preserve its Monopoly

53. Faced with a direct threat to its monopoly, Questcor acted to preserve its market dominance and its ability to charge extraordinary prices for Acthar. It swept in and secretly negotiated a deal to buy the rights to Synacthen from Novartis.

54. On June 11, 2013, the very day that Retrophin and Novartis were to sign their agreement, Questcor acquired the rights to Synacthen. The acquisition was closed on the day of the announcement. Questcor made no Premerger Notification filing with the Department of Justice and the Federal Trade Commission under the Hart Scott Rodino Act Antitrust Improvements Act of 1976. Nor did it observe the waiting period provided by the Hart Scott Act before closing the acquisition.

55. As part of the Agreement, the entire risk of an antitrust challenge to the transaction is borne by Questcor. The Agreement between Novartis and Questcor provides that Novartis receives the full consideration it is entitled to from Questcor even if the US antitrust enforcement agencies (The Federal Trade Commission or the Department of Justice) force Questcor to divest its rights in Synacthen. If such a divestiture occurs, the Agreement provides that Novartis keeps the entire $60 million that Questcor has paid it and Questcor will make all future milestone payments required by the Agreement – an amount in excess of $75 million. In short, the acquisition of the rights to Synacthen was so important to Questcor that it put at least $135 million at risk to keep Synacthen out of Retrophin's hands. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

56. Questcor's acquisition of the rights to Synacthen unreasonably restrained trade, maintained Questcor's monopolies and may result in a substantial lessening of competition in the Relevant Markets. As a result of Questcor's acquisition of the

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rights to Synacthen, prices to patients and payors for Acthar will remain at monopoly levels; patients who are unable to pay for the drug will not be been able to get it; other patients who are forced by Questcor's pricing to limit their dosages of the drug will not be able to take the medically prescribed amounts; and Retrophin will not earn the substantial profits it expected to earn from selling Synacthen at a fraction of the price Questcor charges for Acthar.

Retrophin Is Continuing to Try to Enter the Relevant Markets

57. Despite Questcor's anticompetitive and monopolistic conduct, Retrophin is continuing to try to enter the Relevant Product Markets. To that end, it has taken the highly unusual step of trying to create from scratch a drug – that it has designated as RE-034 – that will match Synacthen. Retrophin is endeavoring to create a new formulation of the drug that will incorporate the same active pharmaceutical ingredient used in Synacthen and match Synacthen's therapeutic effects for patients suffering from Infantile Spasms and Nephrotic Syndrome.

58. Retrophin's efforts to develop RE-034 will take substantial time and money and will require FDA approval. It will also require that the drug successfully complete both Phase I and Phase III clinical trials for both Infantile Spasms and Nephrotic Syndrome. There is no guarantee that RE-034 will succeed in the clinical trials or that Retrophin will succeed in obtaining FDA approval or entering the Relevant Markets.

59. Entering the Relevant Markets through RE-034 is more difficult, risky and time consuming than entering those markets through Synacthen. Synacthen is an existing product that has been manufactured and used outside of the US for decades in the treatment of a variety of illnesses, including Infantile Spasms and Nephrotic Syndrome. The owner of the rights to Synacthen has the information, know-how and ability to manufacture the drug and has decades of clinical data from outside the United States that can be used to facilitate and speed the regulatory approval process

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in the US. Retrophin will need to develop all of that knowledge from scratch in seeking to enter the Relevant Markets with RE-034.

60. Entering the Relevant Markets through RE-034 will be more difficult, less likely to succeed and take longer than entry into those markets through the acquisition of Synacthen. Questcor's conduct has delayed, and may entirely foreclose, Retrophin from entering the Relevant Markets.

Questcor Has Damaged Competition in the Relevant Markets and Has Caused Retrophin to Suffer Both Injury in Fact and Antitrust Injury

61. Questcor's unlawful acquisition of the rights to Synacthen has foreclosed or delayed Retrophin from entering the Relevant Markets, has restrained trade, and has preserved and entrenched Questcor's monopoly and may substantially lessen competition. As a result, competition in the Relevant Markets has been damaged and Retrophin has been injured. Those injuries are intertwined and inseparable. Excluding or delaying Retrophin from entering the Relevant Markets with Synacthen was and is an integral aspect of Questcor's anticompetitive conduct.

62. Retrophin has suffered and continues to suffer injury in fact from Questcor's acquisition of the rights to Synacthen and the preservation of its monopoly.

63. Retrophin has suffered and continues to suffer antitrust injury from Questcor's acquisition of the rights to Synacthen and the preservation of its monopoly. Retrophin has been injured directly as a result of Questcor's unlawful conduct. Retrophin is a potential entrant into the Relevant Markets and, but for Questcor's unlawful conduct, would be entering those markets with Synacthen. There are no aspects of Questcor's conduct that are beneficial to competition. Retrophin's injury is an integral aspect of Questcor's unlawful conduct; flows from that which renders Questcor's conduct unlawful; and its injury is of the type the antitrust laws were intended to prevent.

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FIRST CAUSE OF ACTION

(COMBINATION IN THE RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT)

64. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 63 as if fully set forth herein.

65. In acquiring the rights to Synacthen, Questcor entered into a contract, conspiracy or combination that unreasonably restrains trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

66. Questcor's acquisition of the rights to Synacthen unlawfully and unreasonably restrains trade by preventing or delaying Retrophin from entering the Relevant Markets and challenging Questcor's market power in those markets.

67. Questcor's violation of Section 1 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

68. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

SECOND CAUSE OF ACTION

(MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT)

69. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 68 as if fully set forth herein.

70. Questcor has monopoly power in the Relevant Markets. In acquiring the rights to Synacthen in the US, Questcor has intentionally acted to maintain and entrench its monopoly position in Relevant Markets, and has done so, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

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2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
310.788.4400 tel 310.788.4471 fax

71. Questcor's violation of Section 2 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

72. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

THIRD CAUSE OF ACTION

(ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT)

73. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 72 as if fully set forth herein.

74. In acquiring the rights to Synacthen, Questcor has engaged in monopolistic and anticompetitive conduct with the specific purpose and intent of monopolizing the Relevant Markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

75. The sole purpose of Questcor's acquisition of the rights to Synacthen is to enable Questcor to gain or maintain a monopoly position in the Relevant Markets.

76. A dangerous probability exists that Questcor has succeeded, and if not restrained, will continue to succeed in monopolizing the Relevant Markets.

77. Questcor's acts of attempted monopolization has unlawfully prevented and delayed Retrophin from entering the Relevant Markets and otherwise injure competition in those markets by reducing choice, inflating prices, and lessening innovation.

78. Questcor's violation of Section 2 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

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79. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

FOURTH CAUSE OF ACTION

(UNLAWFUL MERGER IN VIOLATION OF SECTION 7 OF THE CLAYTON ACT)

80. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 79 as if fully set forth herein.

81. Questcor's acquisition of the rights to Synacthen is likely to substantially lessen competition in interstate trade and commerce in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

82. Questcor's acquisition of the rights to Synacthen is likely to result in a substantial lessening of competition in the Relevant Markets.

83. Questcor's violation of Section 7 of the Clayton Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

84. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

FIFTH CAUSE OF ACTION

(VIOLATION OF CALIFORNIA ANTITRUST LAWS)

85. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 84 as if fully set forth herein.

86. In acquiring the rights to Synacthen, Questcor entered into and engaged in a continuing unlawful trust in restraint of the trade and commerce described above in violation of the California antitrust laws referenced below. Questcor has acted in violation of these laws in an effort to maintain, entrench, and/or create a monopoly,

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and otherwise injure competition in the Relevant Markets. Questcor's conduct substantially affected commerce in California.

87. In acquiring the rights to Synacthen in the US, Questcor has maintained and entrenched its monopoly position in the Relevant Markets.

88. Questcor's acquisition of the rights to Synacthen is likely to result in a substantial lessening of competition in the Relevant Markets.

89. By reason of the foregoing, Questcor violated California's Cartwright Act, California Business and Professions Code §§ 16720 *et seq.*

90. Questcor's violation of California's Cartwright Act, California Business and Professions Code §§ 16720 *et seq.* has caused, and will cause, damages to Retrophin in an amount to be determined at trial, with such damages to be trebled.

91. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

SIXTH CAUSE OF ACTION

(UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE § 17200 *ET SEQ.*)

92. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 91 as if fully set forth herein.

93. California Unfair Competition Law, Business and Professions Code Section 17200 *et seq.*, provides that "unfair competition shall mean and include any unlawful, unfair or fraudulent business act."

94. Questcor's conduct as alleged herein meets the "unlawfulness" prong of California Business and Professions Code §§ 17200 *et seq.* Questcor has committed and continues to commit unlawful business practices by illegally acquiring the rights to Synacthen and engaging in anticompetitive and monopolistic conduct in violation of antitrust laws.

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95. Questcor's conduct as alleged herein also meets the "unfair" prong of California Business and Professions Code §§ 17200 *et seq*. Questcor's anticompetitive and monopolistic conduct harms the public interest, threatens an incipient violation of an antitrust law and/or violates the policy or spirit of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition.

96. Pursuant to California Business and Professions Code § 17203, Retrophin seeks the disgorgement of Questcor's profits earned by its unlawful and/or unfair business practices to the extent it constitutes restitution to Retrophin.

97. Pursuant to California Business and Professions Code § 17203, Retrophin seeks an order of this court enjoining Questcor from continuing to engage, use, or employ the unlawful and/or unfair business practices complained of herein.

98. Questcor's wrongful conduct has caused and, if it continues, will continue to cause irreparable harm to Retrophin that cannot be fully compensated by money and for which Retrophin has no adequate remedy at law. Retrophin is thus entitled to permanent injunctive relief preventing Questcor from continuing to engage in the conduct alleged in this Complaint.

PRAYER FOR RELIEF

WHEREFORE, Retrophin respectfully demands judgment against Questcor:

A. DECLARING that Questcor's acquisition of the rights to Synacthen is an unlawful contract, combination or conspiracy in restraint of trade in violation of Section 1 of the Sherman Act;

B. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes unlawful monopolization of the Relevant Markets in violation of Section 2 of the Sherman Act;

C. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes an unlawful attempt to monopolize the Relevant Markets in violation of Section 2 of the Sherman Act;

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D. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes an acquisition that may result in a substantial lessening of competition in the Relevant Markets in violation of Section 7 of the Clayton Act;

E. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes an unlawful trust in restraint of trade and commerce in violation of California Business and Professions Code §§ 16720 *et seq.*;

F. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes unfair competition in violation of California Business and Professions Code § 17200 *et seq.*;

G. PERMANENTLY ENJOINING Questcor from enforcing or maintaining its Rights to Synacthen under its agreement with Novartis or any similar formal or informal agreement;

H. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of Section 1 of the Sherman Act;

I. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of Section 2 of the Sherman Act;

J. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of Section 7 of the Clayton Act;

K. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of California Business and Professions Code §§ 16720, *et seq.*;

L. PERMANENTLY ENJOINING Questcor from engaging in further unlawful and/or unfair business practices in violation of California Business and Professions Code § 17200 *et seq.*;

M. DISGORGING any profits generated by Questcor as a result of its unlawful and/or unfair business practices to the extent it constitutes restitution to Retrophin;

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N. AWARDING Retrophin damages in an amount to be proved at trial, such damages to be trebled, including its costs and attorneys' fees, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15 and/or California's Cartwright Act, California Business and Professions Code §§ 16720, *et seq.*;

O. AWARDING Retrophin its costs, expenses and attorneys' fees incurred in connection with the action;

P. AWARDING Retrophin interest to the maximum extent permitted by law; and

Q. GRANTING Retrophin such other and further relief as this Court deems just and proper.

Dated: January 7, 2014

KATTEN MUCHIN ROSENMAN LLP

By: K. Holland

Kristin L. Holland
Attorneys for Plaintiff Retrophin, Inc.

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Katten Muchin Rosenman LLP
2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
310.788.4400 tel 310.788.4471 fax

DEMAND FOR JURY TRIAL

Retrophin hereby demands a trial by jury on all of its claims and causes of action.

Dated: January 7, 2014

KATTEN MUCHIN ROSENMAN LLP

By: K. Holland

Kristin L. Holland
Attorneys for Plaintiff Retrophin, Inc.

Katten
Katten Muchin Rosenman LLP
2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
310.788.4400 tel 310.788.4471 fax

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA

CIVIL COVER SHEET

I. (a) PLAINTIFFS (Check box if you are representing yourself ☐)

Retrophin, Inc.

DEFENDANTS (Check box if you are representing yourself ☐)

Questcor Pharmaceuticals, Inc.

(b) County of Residence of First Listed Plaintiff New York, NY
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Orange, CA
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.
Katten Muchin Rosenman LLP
2029 Century Park East, Suite 2600
Los Angeles, CA 90067-3012
310-788-4400

Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

N/A

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1. U.S. Government Plaintiff
☒ 3. Federal Question (U.S. Government Not a Party)
☐ 2. U.S. Government Defendant
☐ 4. Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES-For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☒ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1. Original Proceeding ☐ 2. Removed from State Court ☐ 3. Remanded from Appellate Court ☐ 4. Reinstated or Reopened ☐ 5. Transferred from Another District (Specify) ☐ 6. Multi-District Litigation

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check "Yes" only if demanded in complaint.)

CLASS ACTION under F.R.Cv.P. 23: ☐ Yes ☒ No ☒ **MONEY DEMANDED IN COMPLAINT:** $ Over $75k, TBD

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
Plaintiff is suing defendant for entering an illegal agreement and engaging in conduct that violates federal and state antitrust and competition laws, 15 U.S.C. §§ 1, 2, 18, and California Business and Professions Code §§ 16720, et seq, California Business and Professions Code §§ 17200, et seq

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 375 False Claims Act
☐ 400 State Reapportionment
☒ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/Etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced & Corrupt Org.
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 850 Securities/Commodities/Exchange
☐ 890 Other Statutory Actions
☐ 891 Agricultural Acts
☐ 893 Environmental Matters
☐ 895 Freedom of Info. Act
☐ 896 Arbitration
☐ 899 Admin. Procedures Act/Review of Appeal of Agency Decision
☐ 950 Constitutionality of State Statutes

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Vet.)
☐ 153 Recovery of Overpayment of Vet. Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment

REAL PROPERTY CONT.
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpratice
☐ 365 Personal Injury-Product Liability
☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
☐ 462 Naturalization Application
☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
☐ 440 Other Civil Rights
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/ Accomodations
☐ 445 American with Disabilities-Employment
☐ 446 American with Disabilities-Other
☐ 448 Education

PRISONER PETITIONS
Habeas Corpus:
☐ 463 Alien Detainee
☐ 510 Motions to Vacate Sentence
☐ 530 General
☐ 535 Death Penalty

Other:
☐ 540 Mandamus/Other
☐ 550 Civil Rights
☐ 555 Prison Condition
☐ 560 Civil Detainee Conditions of Confinement

FORFEITURE/PENALTY
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 740 Railway Labor Act
☐ 751 Family and Medical Leave Act
☐ 790 Other Labor Litigation
☐ 791 Employee Ret. Inc. Security Act

PROPERTY RIGHTS
☐ 820 Copyrights
☐ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405 (g))
☐ 864 SSID Title XVI
☐ 865 RSI (405 (g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: CV14-00026

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII. VENUE: Your answers to the questions below will determine the division of the Court to which this case will most likely be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

Question A: Was this case removed from state court? ☐ Yes ☒ No If "no," go to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	STATE CASE WAS PENDING IN THE COUNTY OF:	INITIAL DIVISION IN CACD IS:
	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	Southern
	☐ Riverside or San Bernardino	Eastern

Question B: Is the United States, or one of its agencies or employees, a party to this action? ☐ Yes ☒ No If "no," go to Question C. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	If the United States, or one of its agencies or employees, is a party, is it:		INITIAL DIVISION IN CACD IS:
	A PLAINTIFF? Then check the box below for the county in which the majority of DEFENDANTS reside.	A DEFENDANT? Then check the box below for the county in which the majority of PLAINTIFFS reside.	
	☐ Los Angeles	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	☐ Orange	Southern
	☐ Riverside or San Bernardino	☐ Riverside or San Bernardino	Eastern
	☐ Other	☐ Other	Western

Question C: Location of plaintiffs, defendants, and claims? (Make only one selection per row)	A. Los Angeles County	B. Ventura, Santa Barbara, or San Luis Obispo Counties	C. Orange County	D. Riverside or San Bernardino Counties	E. Outside the Central District of California	F. Other
Indicate the location in which a majority of plaintiffs reside:	☐	☐	☐	☐	☒	☐
Indicate the location in which a majority of defendants reside:	☐	☐	☒	☐	☐	☐
Indicate the location in which a majority of claims arose:	☐	☐	☒	☐	☐	☐

C.1. Is either of the following true? If so, check the one that applies:

☒ 2 or more answers in Column C

☐ only 1 answer in Column C and no answers in Column D

Your case will initially be assigned to the SOUTHERN DIVISION.
Enter "Southern" in response to Question D, below.

If none applies, answer question C2 to the right. →

C.2. Is either of the following true? If so, check the one that applies:

☐ 2 or more answers in Column D

☐ only 1 answer in Column D and no answers in Column C

Your case will initially be assigned to the EASTERN DIVISION.
Enter "Eastern" in response to Question D, below.

If none applies, go to the box below. ↓

Your case will initially be assigned to the WESTERN DIVISION.
Enter "Western" in response to Question D below.

Question D: Initial Division?	INITIAL DIVISION IN CACD
Enter the initial division determined by Question A, B, or C above: →	Southern Division

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

IX(a). IDENTICAL CASES: Has this action been previously filed **in this court** and dismissed, remanded or closed? ☒ NO ☐ YES

If yes, list case number(s): _____

IX(b). RELATED CASES: Have any cases been previously filed **in this court** that are related to the present case? ☒ NO ☐ YES

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)
- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

X. SIGNATURE OF ATTORNEY (OR SELF-REPRESENTED LITIGANT): _____ DATE: 1/7/2014

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet).

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))

(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

ELECTRONICALLY FILED
2019 May 23 11:06 AM
CLERK OF COURT

SUMMONS IN CIVIL ACTION

Docket No. _____

(•) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

ACCREDO HEALTH GROUP, INC.
1640 Century Center Parkway
Memphis, TN 38134

Method of Service:

( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

You are hereby summoned and required to defend a civil action by filing your answer with the Clerk of the Court and serving a copy of your answer to the Complaint on Patrick Ardis, R.H. Chip Chockley, Daniel Parish Plaintiff's attorney, whose address is 5810 Shelby Oaks Drive, Memphis, TN, 38134 telephone 901-763-3336 within THIRTY (30) DAYS after this summons has been served upon you, not including the day of service. If you fail to do so, a judgment by default may be taken against you for the relief demanded in the Complaint.

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master

TESTED AND ISSUED _____ By _____, D.C.

TO THE DEFENDANT:

NOTICE; Pursuant to Chapter 919 of the Public Acts of 1980, you are hereby given the following notice:
Tennessee law provides a ten thousand dollar ($10,000) personal property exemption from execution or seizure to satisfy a judgment. If a judgment should be entered against you in this action and you wish to claim property as exempt, you must file a written list, under oath, of the items you wish to claim as exempt with the Clerk of the Court. The list may be filed at any time and may be changed by you thereafter as necessary; however, unless it is filed before the judgment becomes final, it will not be effective as to any execution or garnishment issued prior to the filing of the list. Certain items are automatically exempt by law and do not need to be listed. These include items of necessary wearing apparel (clothing) for yourself and your family and trunks or other receptacles necessary to contain such apparel, family portraits, the family Bible and school books. Should any of these items be seized, you would have the right to recover them. If you do not understand your exemption right or how to exercise it, you may wish to seek the counsel of a lawyer.

FOR AMERICANS WITH DISABILITIES ACT (ADA) ASSISTANCE ONLY, CALL (901) 222-2341

I, TEMIIKA D. GIPSON / DONNA RUSSELL, Clerk of the Court, Shelby County, Tennessee, certify this to be a true and accurate copy as filed this

_____ 20__

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master By: _____, D.C.

RETURN OF SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE** SERVED THE WITHIN SUMMONS:

By delivering on the _____ day of _____, 20____ at _____ M. a copy of the summons and a copy of the Complaint to the following Defendant _____

at _____

_____ By: _____

Signature of person accepting service Sheriff or other authorized person to serve process

RETURN OF NON-SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE NOT** SERVED THE WITHIN SUMMONS:

To the named Defendant _____

because _____ is (are) not to be found in this County after diligent search and inquiry for the following reason(s): _____

This _____ day of _____, 20_____.

By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

Case Number: CT-2275-19

Type: SUMMONS ISSD TO MISC

Kathryn Howard, DC

Electronically signed on 05/23/2019 03:24:12 PM

(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

ELECTRONICALLY FILED
2019 May 23 11:06 AM
CLERK OF COURT

SUMMONS IN CIVIL ACTION

Docket No. _____

(•) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

CURASCRIPT, INC. doing business as CURASCRIPT SD
255 Technology Park
Lake Mary, FL 32746

Method of Service:

( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

You are hereby summoned and required to defend a civil action by filing your answer with the Clerk of the Court and serving a copy of your answer to the Complaint on Patrick Ardis, R.H. Chip Chockley, Daniel Parish Plaintiff's attorney, whose address is 5810 Shelby Oaks Drive, Memphis, TN, 38134 telephone 901-763-3336 within THIRTY (30) DAYS after this summons has been served upon you, not including the day of service. If you fail to do so, a judgment by default may be taken against you for the relief demanded in the Complaint.

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master

TESTED AND ISSUED _____ By _____, D.C.

TO THE DEFENDANT:

NOTICE; Pursuant to Chapter 919 of the Public Acts of 1980, you are hereby given the following notice:
Tennessee law provides a ten thousand dollar ($10,000) personal property exemption from execution or seizure to satisfy a judgment. If a judgment should be entered against you in this action and you wish to claim property as exempt, you must file a written list, under oath, of the items you wish to claim as exempt with the Clerk of the Court. The list may be filed at any time and may be changed by you thereafter as necessary; however, unless it is filed before the judgment becomes final, it will not be effective as to any execution or garnishment issued prior to the filing of the list. Certain items are automatically exempt by law and do not need to be listed. These include items of necessary wearing apparel (clothing) for yourself and your family and trunks or other receptacles necessary to contain such apparel, family portraits, the family Bible and school books. Should any of these items be seized, you would have the right to recover them. If you do not understand your exemption right or how to exercise it, you may wish to seek the counsel of a lawyer.

FOR AMERICANS WITH DISABILITIES ACT (ADA) ASSISTANCE ONLY, CALL (901) 222-2341

I, TEMIIKA D. GIPSON / DONNA RUSSELL, Clerk of the Court, Shelby County, Tennessee, certify this to be a true and accurate copy as filed this

_____ 20__

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master By: _____, D.C.

RETURN OF SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE** SERVED THE WITHIN SUMMONS:

By delivering on the _____ day of _____, 20____ at _____ M. a copy of the summons and a copy of the Complaint to the following Defendant _____

at _____

_____ By: _____

Signature of person accepting service Sheriff or other authorized person to serve process

RETURN OF NON-SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE NOT** SERVED THE WITHIN SUMMONS:

To the named Defendant _____

because _____ is (are) not to be found in this County after diligent search and inquiry for the following reason(s): _____

This _____ day of _____, 20_____.

By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

Case Number: CT-2275-19

Type: SUMMONS ISSD TO MISC

Kathryn Howard, DC

Electronically signed on 05/23/2019 03:24:12 PM

(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

ELECTRONICALLY FILED
2019 May 23 11:06 AM
CLERK OF COURT

SUMMONS IN CIVIL ACTION

Docket No. _____

(•) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

JAMES A. TUMLIN, M.D.
Nephrology Associates of Chattanooga
2300 E. 3rd Street
Chattanooga, TN 37404

Method of Service:

( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

You are hereby summoned and required to defend a civil action by filing your answer with the Clerk of the Court and serving a copy of your answer to the Complaint on Patrick Ardis, R.H. Chip Chockley, Daniel Parish Plaintiff's attorney, whose address is 5810 Shelby Oaks Drive, Memphis, TN, 38134 telephone 901-763-3336 within THIRTY (30) DAYS after this summons has been served upon you, not including the day of service. If you fail to do so, a judgment by default may be taken against you for the relief demanded in the Complaint.

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master

TESTED AND ISSUED _____ By _____, D.C.

TO THE DEFENDANT:

NOTICE; Pursuant to Chapter 919 of the Public Acts of 1980, you are hereby given the following notice:
Tennessee law provides a ten thousand dollar ($10,000) personal property exemption from execution or seizure to satisfy a judgment. If a judgment should be entered against you in this action and you wish to claim property as exempt, you must file a written list, under oath, of the items you wish to claim as exempt with the Clerk of the Court. The list may be filed at any time and may be changed by you thereafter as necessary; however, unless it is filed before the judgment becomes final, it will not be effective as to any execution or garnishment issued prior to the filing of the list. Certain items are automatically exempt by law and do not need to be listed. These include items of necessary wearing apparel (clothing) for yourself and your family and trunks or other receptacles necessary to contain such apparel, family portraits, the family Bible and school books. Should any of these items be seized, you would have the right to recover them. If you do not understand your exemption right or how to exercise it, you may wish to seek the counsel of a lawyer.

FOR AMERICANS WITH DISABILITIES ACT (ADA) ASSISTANCE ONLY, CALL (901) 222-2341

I, TEMIIKA D. GIPSON / DONNA RUSSELL, Clerk of the Court, Shelby County, Tennessee, certify this to be a true and accurate copy as filed this

_____ 20__

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master By: _____, D.C.

RETURN OF SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE** SERVED THE WITHIN SUMMONS:

By delivering on the _____ day of _____, 20____ at _____ M. a copy of the summons and a copy of the Complaint to the following Defendant _____

at _____

_____ By: _____

Signature of person accepting service Sheriff or other authorized person to serve process

RETURN OF NON-SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE NOT** SERVED THE WITHIN SUMMONS:

To the named Defendant _____

because _____ is (are) not to be found in this County after diligent search and inquiry for the following reason(s): _____

This _____ day of _____, 20_____.

By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

Case Number: CT-2275-19

Type: SUMMONS ISSD TO MISC

Kathryn Howard, DC

Electronically signed on 05/23/2019 03:24:12 PM

(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

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SUMMONS IN CIVIL ACTION

Docket No. _____

(•) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

EXPRESS SCRIPTS HOLDING COMPANY
1 Express Way
Saint Louis, MO 63121

Method of Service:
( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

You are hereby summoned and required to defend a civil action by filing your answer with the Clerk of the Court and serving a copy of your answer to the Complaint on Patrick Ardis, R.H. Chip Chockley, Daniel Parish Plaintiff's attorney, whose address is 5810 Shelby Oaks Drive, Memphis, TN, 38134 telephone 901-763-3336 within THIRTY (30) DAYS after this summons has been served upon you, not including the day of service. If you fail to do so, a judgment by default may be taken against you for the relief demanded in the Complaint.

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master

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TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master By: _____, D.C.

RETURN OF SERVICE OF SUMMONS

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By delivering on the _____ day of _____, 20____ at _____ M. a copy of the summons and a copy of the Complaint to the following Defendant _____

at _____

_____ By: _____

Signature of person accepting service Sheriff or other authorized person to serve process

RETURN OF NON-SERVICE OF SUMMONS

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To the named Defendant _____

because _____ is (are) not to be found in this County after diligent search and inquiry for the following reason(s): _____

This _____ day of _____, 20_____.

By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

Case Number: CT-2275-19

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Kathryn Howard, DC

Electronically signed on 05/23/2019 03:24:12 PM

(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

ELECTRONICALLY FILED
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CLERK OF COURT

SUMMONS IN CIVIL ACTION

Docket No. _____

(●) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

EXPRESS SCRIPTS, INC.
1 Express Way
Saint Louis, MO 63121

Method of Service:

( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

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TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master

TESTED AND ISSUED _____ By _____, D.C.

TO THE DEFENDANT:

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FOR AMERICANS WITH DISABILITIES ACT (ADA) ASSISTANCE ONLY, CALL (901) 222-2341

I, TEMIIKA D. GIPSON / DONNA RUSSELL, Clerk of the Court, Shelby County, Tennessee, certify this to be a true and accurate copy as filed this

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TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master By: _____, D.C.

RETURN OF SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE** SERVED THE WITHIN SUMMONS:

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Signature of person accepting service Sheriff or other authorized person to serve process

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By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

Case Number: CT-2275-19

Type: SUMMONS ISSD TO MISC

Kathryn Howard, DC

Electronically signed on 05/23/2019 03:24:12 PM

(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
FOR THE THIRTIETH JUDICIAL DISTRICT AT MEMPHIS

ELECTRONICALLY FILED
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CLERK OF COURT

SUMMONS IN CIVIL ACTION

Docket No. _____

(•) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

MALLINCKRODT ARD, INC., formally known as QUESTCOR PHARMACEUTICALS, INC.
675 McDonnell Boulevard
Hazelwood, MO 63042

Method of Service:
( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

You are hereby summoned and required to defend a civil action by filing your answer with the Clerk of the Court and serving a copy of your answer to the Complaint on Patrick Ardis, R.H. Chip Chockley, Daniel Parish Plaintiff's attorney, whose address is 5810 Shelby Oaks Drive, Memphis, TN, 38134 telephone 901-763-3336 within THIRTY (30) DAYS after this summons has been served upon you, not including the day of service. If you fail to do so, a judgment by default may be taken against you for the relief demanded in the Complaint.

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master

TESTED AND ISSUED _____ By _____, D.C.

TO THE DEFENDANT:

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FOR AMERICANS WITH DISABILITIES ACT (ADA) ASSISTANCE ONLY, CALL (901) 222-2341

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The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

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(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
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SUMMONS IN CIVIL ACTION

Docket No. _____

(●) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

MALLINCKRODT PLC
3 Lotus Park, The Causeway
Staines-upon-Thames
Surrey, TW18 3 AG

Method of Service:

( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

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TEMIIKA D. GIPSON , Clerk / DONNA RUSSELL, Clerk and Master By: _____, D.C.

RETURN OF SERVICE OF SUMMONS

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By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

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(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
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SUMMONS IN CIVIL ACTION

Docket No. _____

(●) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

PRIORITY HEALTHCARE CORP.
1680 Century Center Parkway
Memphis, TN 38134-8827

Method of Service:
( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

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By: _____

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The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

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(CIRCUIT/CHANCERY) COURT OF TENNESSEE
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Docket No. _____

(●) Lawsuit
( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

UNITED BIOSOURCE CORPORATION
n/k/a UNITED BIOSOURCE LLC
920 Harvest Drive
Blue Bell, PA 19422

Method of Service:
( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

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_____ By: _____

Signature of person accepting service Sheriff or other authorized person to serve process

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By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

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(CIRCUIT/CHANCERY) COURT OF TENNESSEE
140 ADAMS AVENUE, MEMPHIS, TENNESSEE 38103
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( ) Divorce

Ad Damnum $ _____

ACUMENT GLOBAL TECHNOLOGIES, INC.	VS	MALLINCKRODT ARD, INC., Formally known as QUESTCOR PHARMACEUTICALS, INC., et al
Plaintiff(s)		Defendant(s)

TO: (Name and Address of Defendant (One defendant per summons))

PRIORITY HEALTHCARE DISTRIBUTION, INC.
doing business as CURASCRIPT SD AND
CURASCRIPT SPECIALTY DISTRIBUTION SD, respectively
1680 Century Center Parkway
Memphis, TN 38134-8827

Method of Service:

( ) Certified Mail
( ) Shelby County Sheriff
( ) Commissioner of Insurance ($)
( ) Secretary of State ($)
( ) Other TN County Sheriff ($)
( ) Private Process Server
( ) Other

($) Attach Required Fees

You are hereby summoned and required to defend a civil action by filing your answer with the Clerk of the Court and serving a copy of your answer to the Complaint on Patrick Ardis, R.H. Chip Chockley, Daniel Parish Plaintiff's attorney, whose address is 5810 Shelby Oaks Drive, Memphis, TN, 38134 telephone 901-763-3336 within THIRTY (30) DAYS after this summons has been served upon you, not including the day of service. If you fail to do so, a judgment by default may be taken against you for the relief demanded in the Complaint.

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master

TESTED AND ISSUED _____ By _____, D.C.

TO THE DEFENDANT:

NOTICE; Pursuant to Chapter 919 of the Public Acts of 1980, you are hereby given the following notice:
Tennessee law provides a ten thousand dollar ($10,000) personal property exemption from execution or seizure to satisfy a judgment. If a judgment should be entered against you in this action and you wish to claim property as exempt, you must file a written list, under oath, of the items you wish to claim as exempt with the Clerk of the Court. The list may be filed at any time and may be changed by you thereafter as necessary; however, unless it is filed before the judgment becomes final, it will not be effective as to any execution or garnishment issued prior to the filing of the list. Certain items are automatically exempt by law and do not need to be listed. These include items of necessary wearing apparel (clothing) for yourself and your family and trunks or other receptacles necessary to contain such apparel, family portraits, the family Bible and school books. Should any of these items be seized, you would have the right to recover them. If you do not understand your exemption right or how to exercise it, you may wish to seek the counsel of a lawyer.

FOR AMERICANS WITH DISABILITIES ACT (ADA) ASSISTANCE ONLY, CALL (901) 222-2341

I, TEMIIKA D. GIPSON / DONNA RUSSELL, Clerk of the Court, Shelby County, Tennessee, certify this to be a true and accurate copy as filed this

_____ 20__

TEMIIKA D. GIPSON, Clerk / DONNA RUSSELL, Clerk and Master By: _____, D.C.

RETURN OF SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE** SERVED THE WITHIN SUMMONS:

By delivering on the _____ day of _____, 20____ at _____ M. a copy of the summons and a copy of the Complaint to the following Defendant _____

at _____

_____ By: _____

Signature of person accepting service Sheriff or other authorized person to serve process

RETURN OF NON-SERVICE OF SUMMONS

I HEREBY CERTIFY THAT I **HAVE NOT** SERVED THE WITHIN SUMMONS:

To the named Defendant _____

because _____ is (are) not to be found in this County after diligent search and inquiry for the following reason(s): _____

This _____ day of _____, 20_____.

By: _____

Sheriff or other authorized person to serve process

The Shelby County, Tennessee Circuit Court

Case Style: ACUMENT GLOBAL TECH VS MALLINCKRODT ARD INC

Case Number: CT-2275-19

Type: SUMMONS ISSD TO MISC

Kathryn Howard, DC

Electronically signed on 05/23/2019 03:24:12 PM

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2019 Jun 05 3:31 PM
CLERK OF COURT

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

NO. CT-2275-19
Div. VII

MALLINCKRODT ARD, INC., *Formally known as* QUESTCOR PHARMACEUTICALS, INC., MALLINCKRODT PLC, EXPRESS SCRIPTS HOLDING COMPANY, EXPRESS SCRIPTS, INC., CURASCRIPT, INC., d/b/a CURASCRIPT, SD, PRIORITY HEALTHCARE CORP. AND PRIORITY HEALTHCARE DISTRIBUTION, INC., d/b/a CURASCRIPT SD AND CURASCRIPT SPECIALTY DISTRIBUTION SD, *respectively*, ACCREDO HEALTH GROUP, INC., UNITED BIOSOURCE CORPORATION, and JAMES A. TUMLIN, M.D.,

Defendants.

NOTICE OF APPEARANCE

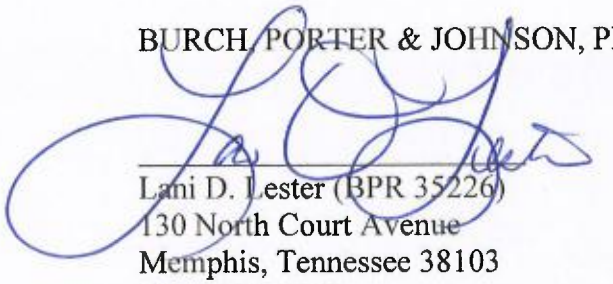
Burch, Porter & Johnson, PLLC, by and through undersigned counsel, hereby gives notice of its appearance as counsel of record in this case for Defendants Express Scripts Holding Company; Express Scripts, Inc.; Curascript, Inc. d/b/a Curascript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD; Accredo Health Group, Inc.; and United Biosource Corporation.

This notice of appearance is without waiver of any defenses which may be available to Defendants Express Scripts Holding Company; Express Scripts, Inc.; Curascript, Inc. d/b/a

Curascript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD; Accredo Health Group, Inc.; and United Biosource Corporation.

Respectfully submitted,

BURCH, PORTER & JOHNSON, PLLC



Lani D. Lester (BPR 35226)
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Attorney for Defendants Express Scripts Holding Company; Express Scripts, Inc.; Curascript, Inc. d/b/a Curascript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD; Accredo Health Group, Inc.; and United Biosource Corporation

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been delivered via U.S. mail this 5th day of June, 2019, to the following:

Patrick M. Ardis
R.H. "Chip" Chockley
Daniel V. Parish
WOLFF ARDIS, P.C.
5810 Shelby Oaks Drive
Memphis, TN 38134

Donald E. Haviland, Jr.
William H. Platt II
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201 S. Maple Way, Suite 110
Ambler, PA 19002

Lani D. Lester

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CLERK OF COURT

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

NO. CT-2275-19
Div. VII

MALLINCKRODT ARD, INC., *Formally known as* QUESTCOR PHARMACEUTICALS, INC., MALLINCKRODT PLC, EXPRESS SCRIPTS HOLDING COMPANY, EXPRESS SCRIPTS, INC., CURASCRIPT, INC., d/b/a CURASCRIPT, SD, PRIORITY HEALTHCARE CORP. AND PRIORITY HEALTHCARE DISTRIBUTION, INC., d/b/a CURASCRIPT SD AND CURASCRIPT SPECIALTY DISTRIBUTION SD, *respectively,* ACCREDO HEALTH GROUP, INC., UNITED BIOSOURCE CORPORATION, and JAMES A. TUMLIN, M.D.,

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Curascript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD; Accredo Health Group, Inc.; and United Biosource Corporation.

Respectfully submitted,

BURCH, PORTER & JOHNSON, PLLC

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William D. Irvine Jr.

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CLERK OF COURT

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

NO. CT-2275-19
Div. VII

MALLINCKRODT ARD, INC., *Formally known as* QUESTCOR PHARMACEUTICALS, INC., MALLINCKRODT PLC, EXPRESS SCRIPTS HOLDING COMPANY, EXPRESS SCRIPTS, INC., CURASCRIPT, INC., d/b/a CURASCRIPT, SD, PRIORITY HEALTHCARE CORP. AND PRIORITY HEALTHCARE DISTRIBUTION, INC., d/b/a CURASCRIPT SD AND CURASCRIPT SPECIALTY DISTRIBUTION SD, *respectively,* ACCREDO HEALTH GROUP, INC., UNITED BIOSOURCE CORPORATION, and JAMES A. TUMLIN, M.D.,

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Curascript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD; Accredo Health Group, Inc.; and United Biosource Corporation.

Respectfully submitted,

BURCH, PORTER & JOHNSON, PLLC

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Attorney for Defendants Express Scripts Holding Company; Express Scripts, Inc.; Curascript, Inc. d/b/a Curascript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD; Accredo Health Group, Inc.; and United Biosource Corporation

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Memphis, TN 38134

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Ambler, PA 19002

Nathan A. Bicks
Nathan A. Bicks

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CLERK OF COURT

IN THE CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES, INC.,

Plaintiff,

v.

NO. CT-2275-19
Div. VII

MALLINCKRODT ARD, INC., *Formally known as* QUESTCOR PHARMACEUTICALS, INC., MALLINCKRODT PLC, EXPRESS SCRIPTS HOLDING COMPANY, EXPRESS SCRIPTS, INC., CURASCRIPT, INC., d/b/a CURASCRIPT, SD, PRIORITY HEALTHCARE CORP. AND PRIORITY HEALTHCARE DISTRIBUTION, INC., d/b/a CURASCRIPT SD AND CURASCRIPT SPECIALTY DISTRIBUTION SD, *respectively,* ACCREDO HEALTH GROUP, INC., UNITED BIOSOURCE CORPORATION, and JAMES A. TUMLIN, M.D.,

Defendants.

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Curascript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD; Accredo Health Group, Inc.; and United Biosource Corporation.

Respectfully submitted,

BURCH, PORTER & JOHNSON, PLLC

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CERTIFICATE OF SERVICE

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William D. Irvine Jr.

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CLERK OF COURT

CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES, INC., Plaintiff, v. MALLINCKRODT ARD, INC., et al., Defendants.	Docket No. CT-2275-19

THE EXPRESS SCRIPTS DEFENDANTS' MOTION TO DISMISS

COME NOW Defendants Express Scripts Holding Company, Express Scripts, Inc., CuraScript, Inc., Priority Healthcare Corp., Priority Healthcare Distribution, Inc. d/b/a CuraScript SD, Accredo Health Group, Inc., and United BioSource Corporation (collectively, the "Express Scripts Entities"), by and through undersigned counsel, and hereby move this Court to dismiss Plaintiff's claims against the Express Scripts Entities pursuant to Tennessee Rule of Civil Procedure 12.02(6) for failure to state a claim upon which relief may be granted. In support of this Motion, the Express Scripts Entities rely on the contemporaneously-filed Memorandum in support.

Respectfully submitted,

BURCH, PORTER & JOHNSON, PLLC

Nathan A. Bicks (BPR #10903)
Lani D. Lester (BPR #35226)
William D. Irvine Jr. (BPR #35193)
130 North Court Avenue
Memphis, Tennessee 38103
(901) 524-5000
Attorney for Defendants Express Scripts Holding Company; Express Scripts, Inc.; CuraScript, Inc.

d/b/a CuraScript, SD; Priority Healthcare Corp.; Priority Healthcare Distribution, Inc. d/b/a CuraScript SD and CuraScript Specialty Distribution SD; Accredo Health Group, Inc.; and United BioSource Corporation

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been delivered via U.S. mail this 23rd day of July, 2019, to the following:

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R.H. "Chip" Chockley
Daniel V. Parish
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Memphis, TN 38134

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Ambler, PA 19002

Nathan A. Bicks

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CLERK OF COURT

CIRCUIT COURT OF SHELBY COUNTY, TENNESSEE
FOR THE THIRTIETH JUDICIAL CIRCUIT AT MEMPHIS

ACUMENT GLOBAL TECHNOLOGIES, INC., Plaintiff, v. MALLINCKRODT ARD, INC., et al., Defendants.	Docket No. CT-2275-19

MEMORANDUM OF LAW IN SUPPORT OF THE EXPRESS SCRIPTS DEFENDANTS' MOTION TO DISMISS

Defendants Express Scripts Holding Company ("ESHC"), Express Scripts, Inc. ("ESI"), CuraScript, Inc., Priority Healthcare Corp., Priority Healthcare Distribution, Inc. d/b/a CuraScript SD ("CuraScript SD"), Accredo Health Group, Inc. ("Accredo"), and United BioSource Corporation ("UBC") (collectively, the "Express Scripts Entities") respectfully submit this Memorandum of Law in support of their Motion to Dismiss the Complaint (the "Complaint" or "Compl.") filed by Plaintiff Acument Global Technologies, Inc. ("Plaintiff" or "Acument") for failure to state a claim under Tennessee Rule of Civil Procedure 12.02(6).

INTRODUCTION

Plaintiff's lawsuit is a textbook example of forum shopping. Plaintiff first brought the ***very same claims*** it asserts here in federal court. On January 25, 2019, the federal court dismissed all of Plaintiff's claims with leave to amend. Rather than amend its complaint, Plaintiff voluntarily dismissed its federal action and re-filed the same claims in this Court—omitting only the federal claims that would have provided federal subject matter jurisdiction.[1]

[1] For this reason, Defendants intend to file a motion under Rule 41.04 to stay this case until Plaintiff pays Defendants' costs and fees associated with litigating Plaintiff's claims in the federal action, *City of Rockford v. Mallinckrodt ARD, Inc.*, No. 17-cv-50107 (N.D. Ill.) (the "Illinois Litigation").

In both this case and in the federal case that was dismissed, Plaintiff asserts that Defendant Mallinckrodt[2] has a monopoly in the market for adrenocorticotropic hormone ("ACTH") drugs because Acthar is the only medication containing ACTH that is approved by the Food & Drug Administration ("FDA"). Plaintiff complains that, as a result of this monopoly, Mallinckrodt charges prices for Acthar that are too high. Plaintiff contends the Express Scripts Entities are liable because Mallinckrodt allegedly preserved its Acthar monopoly, in part, through (i) an exclusive distribution agreement between Mallinckrodt and Defendant CuraScript SD; and (ii) the patient support program provided to Mallinckrodt by Defendant UBC, which is called the Acthar Support and Access Program ("ASAP").

Plaintiff's claims should fare no better in this Court than they did in the federal court that already dismissed them. ***First***, Plaintiff still lacks antitrust standing to assert its Tennessee Trade Practices Act ("TTPA") claims (Counts I and II) and fails to allege that the Express Scripts Entities engaged in anticompetitive conduct under the TTPA. Plaintiff paid for Acthar under contracts with CVS Caremark, a non-party to this lawsuit. As the federal court found, those separate contracts break the chain of causation that links the alleged conduct by the Express Scripts Entities to the purported damages sustained by Plaintiff.

Plaintiff's TTPA claims also fail for the independent reason that Plaintiff does not allege that the Express Scripts Entities engaged in anticompetitive conduct. Exclusive distribution contracts with a monopolist like Mallinckrodt are not illegal unless they harm competition by foreclosing competition from one of the monopolist's actual or potential competitors. In this case, the Complaint repeatedly pleads that Acthar has no competition, which means the challenged agreements have nothing to do with Mallinckrodt's ability to maintain its monopoly.

[2] This brief refers to Mallinckrodt ARD, Inc. and Mallinckrodt plc collectively as "Mallinckrodt." Unless otherwise noted, references to "Mallinckrodt" include its predecessor Questcor Pharmaceuticals, Inc. ("Questcor").

Second, the Tennessee Consumer Protection Act ("TCPA") claim (Count III) should be dismissed because it is based on the same purportedly anticompetitive conduct as the TTPA claim—which is deficient for the reasons identified above—and, in any event, anticompetitive conduct is not an unfair or deceptive practice under the TCPA. Plaintiff also fails to allege that, before it decided to cover its beneficiary's Acthar prescriptions, it read, heard, or was otherwise aware of any purported misrepresentation by any Defendant.

Third, Plaintiff's fraud claim (Count V) fails because Plaintiff does not allege any purportedly false statement with the particularity required by Rule 9.02 of the Tennessee Rules of Civil Procedure. And like its TCPA claim, Plaintiff's fraud claim also fails because Plaintiff does not adequately allege that it relied on any purported misrepresentation to its detriment, including when it decided to reimburse its beneficiary's Acthar prescriptions.

Fourth, Plaintiff's claims for unjust enrichment (Count IV) and conspiracy to defraud (Count VI) are based on the same deficient allegations as Plaintiff's other claims and, therefore, fail for the same reasons. And as the federal court held, Plaintiff's unjust enrichment claim also fails because Plaintiff does not allege that it has exhausted any remedy it may have against CVS Caremark or that attempting to do so would be futile.

For the foregoing reasons, and just as the federal court did before it, this Court should dismiss each of Plaintiff's claims against the Express Scripts Entities.

FACTUAL ALLEGATIONS

A. Mallinckrodt's Alleged Monopoly

According to the Complaint, "Acthar has a 100% share of the market for ACTH drugs in Tennessee and throughout the United States. No other ACTH drug is FDA-approved for therapeutic use." (Compl. ¶ 234.) Acthar treats, among other conditions, infantile spasms, a rare form of seizures (*id.* ¶¶ 52, 57), and nephrotic syndrome, a kidney disorder (*id.* ¶ 177).

Mallinckrodt acquired the rights to Acthar in 2014 when it bought Questcor. (*Id.* ¶ 4.) Thus, "Mallinckrodt manufactures, markets, distributes and sells" the only therapeutic ACTH product sold in the United States. (*Id.* ¶ 3.)

Plaintiff further alleges that the purported "ACTH market[] is characterized by high barriers to entry" because:

> Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require ***significant time, costs, and effort***, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval.

(*Id.* ¶ 235 (emphasis added).) Thus, Acthar also "has significant durability in the marketplace because it will be very difficult for this product to be replicated in any way by a generic." (*Id.* ¶ 235 (internal quotations omitted).) In 2010, the FDA granted Acthar "orphan drug status," which provided Questcor with an exclusivity period of seven years during which no other ACTH product could receive FDA approval to treat infantile spasms. (*Id.* ¶ 57.)

In 2013, Questcor allegedly entrenched its monopolistic hold on the ACTH drug market by acquiring the rights to develop, market, and sell Synacthen (*id.* ¶ 255), "a synthetically derived ACTH medication, which, like Acthar, could be injected intra-muscularly" (*id.* ¶ 189). Plaintiff alleges that Synacthen is used as an alternative to Acthar in other countries, though it has not been approved for marketing in the United States because Questcor and Mallinckrodt declined to seek such approval. (*Id.* ¶¶ 249, 256.)

"In January 2014, Retrophin [another pharmaceutical company] sued Questcor (n/k/a Mallinckrodt) for antitrust violations" (*id.* ¶ 257), and "Mallinckrodt chose to settle the Retrophin lawsuit for $15.5 million" (*id.* ¶ 261). In January 2017, the Federal Trade Commission ("FTC") sued Mallinckrodt for unlawful monopolistic conduct based on Questcor's

acquisition of the Synacthen rights and entered a settlement pursuant to which Mallinckrodt paid $100 million. (*Id.* ¶ 267.) No Express Scripts Entity was named a defendant in Retrophin's or the FTC's lawsuits.

As a result of Mallinckrodt's alleged monopoly in the purported market for ACTH drugs and the absence of any "competitive constraints" (*id.* ¶ 230) on the ACTH market, Plaintiff asserts that "Mallinckrodt has been able to raise prices unchecked" (*id.* ¶ 229).

B. The Alleged Involvement of CuraScript SD, Accredo, and UBC

Plaintiff alleges that CuraScript SD was the exclusive distributor of Acthar between July 2007 and 2017.[3] (*Id.* ¶¶ 60-61.) Plaintiff further alleges that, in July 2007, Questcor began requesting that doctors submit new Acthar prescriptions through ASAP, which is administered by UBC. (*Id.* ¶ 100.) Plaintiff describes the interplay between Accredo, CuraScript, and UBC as follows:

> Once the patient (or their physician) contacts Mallinckrodt for a prescription of Acthar, they are directed to UBC. Otherwise, patients and/or their providers contact UBC directly, as directed by the Acthar Start Form at attached as Exhibit "A" hereto. UBC then serves as the "HUB" for Mallinckrodt and the Express Scripts Entities. UBC also serves as the primary interface with other PBMs, like CVS/Caremark utilized by Acument in 2015-2016 when it paid for Acthar. As the HUB, UBC confirms the prescription by the provider with a specialty pharmacy, whether Accredo or some other specialty pharmacy. UBC then confirms the patient's insurance coverage or other source of payment, whether with Express Scripts, CVS/Caremark or some other PBM or insurer. UBC then arranges for Acthar to be delivered directly to the patient by CuraScript.

(*Id.* ¶ 79.) To receive services from UBC, the patient signs a form that authorizes "Mallinckrodt reimbursement support personnel and United BioSource Corporation" to perform certain functions (*id.* ¶ 81) (quoting Compl. Ex. A), including "'reimbursement and coverage support,

[3] *See also* Compl. Ex. B (Mallinckrodt "Urgent Product Alert," dated July 2, 2007, stating that "***[e]ffective August 1, 2007, Acthar Gel . . . will be available exclusively through Specialty Pharmacy Distribution***" and that "[b]eginning July 16, 2007, hospitals should place all stock orders with CuraScript [SD]" (emphasis in original)).

patient assistance and access programs, medication shipment tracking, and home injection training'" (Compl. Ex. A, at 3).

C. The Alleged Involvement of Express Scripts, Inc.

ESI is a pharmacy benefit manager ("PBM"), which provides to its third-party payor ("TPP") clients services such as "retail pharmacy claims processing, formulary management, utilization management and home delivery pharmacy services." (Compl. ¶ 90 (citation omitted).) It is important to note that Plaintiff is not one of ESI's clients. (*Id.* ¶ 98.)

Plaintiff alleges that certain ESI executives made public statements concerning Acthar, such as those attributed to ESI's "Senior Vice President [of] Supply Chain and Specialty Pharma, Everett Neville." (*Id.* ¶ 163.) Neville is accused of stating "***that [Acthar] is vastly overpriced for the value***" during a "private investor conference call hosted by Citi" in 2017. (*Id.* ¶¶ 163-64 (emphasis in original) (citation omitted).) On that same call, ESI's Chief Medical Officer, Steven Miller, stated that Acthar's "real use should be very, very limited. It's an old drug. There's better products in the marketplace and so we're going to continue to be very vigilant in our utilization management." (*Id.* ¶ 172 (citation omitted).)

D. Plaintiff Accessed Acthar through CVS Caremark and CVS Caremark Specialty, Not the Express Scripts Entities

In 2015 and 2016, CVS Caremark—Plaintiff's PBM at the time—charged Plaintiff for Acthar prescribed to one of its beneficiaries to treat nephrotic syndrome (*id.* ¶¶ 24-25, 175), "at a discounted price[] based on AWP [average wholesale price]." (*Id.* ¶ 307.) "The Acument patient at issue dealt with CVS Caremark Specialty," rather than Accredo, "for their [*sic*] fulfillment of Acthar." (*Id.* ¶ 98.) ESI served as Plaintiff's PBM only ***prior*** to December 2015—i.e., ***before*** Plaintiff was charged for its beneficiary's Acthar prescription. (*Id.* ¶¶ 24, 307.)

ARGUMENT

"[F]or a complaint to survive a motion to dismiss [under Rule 12.02(6)], the facts pleaded, and the inferences reasonably drawn from these facts, must raise the pleader's right to relief beyond the speculative level. Moreover, courts are not required to accept as true assertions that are merely legal arguments or legal conclusions couched as facts." *West v. Schofield*, 468 S.W.3d 482, 489 (Tenn. 2015) (internal quotation marks and citations omitted). A complaint should be dismissed for failure to state a claim if "it appears that the plaintiff can prove no set of facts in support of his or her claim that would warrant relief." *Kincaid v. SouthTrust Bank*, 221 S.W.3d 32, 37 (Tenn. Ct. App. 2006).

Rule 9.02 applies to Plaintiff's claims under the TCPA and for fraud. *See Diggs v. Lasalle Nat'l Bank Ass'n*, 387 S.W.3d 559, 565 (Tenn. Ct. App. 2012) (applying Rule 9.02 to fraud claim); *Harvey v. Ford Motor Credit Co.*, 8 S.W.3d 273, 275 (Tenn. Ct. App. 1999) (TCPA claim "must be scrutinized in light of [Rule 9.02's particularity] requirements"). Rule 9.02 requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Tenn. R. Civ. P. 9.02. To satisfy Rule 9.02's particularity requirement, a complaint must allege "what representations were made and by whom." *PNC Multifamily Capital Inst. Fund XXVI Ltd. P'ship v. Bluff City Cmty. Dev. Corp.*, 387 S.W.3d 525, 549 (Tenn. Ct. App. 2012). Thus, a claim subject to Rule 9.02 should be dismissed where "[t]he exact misrepresentation(s) . . . are difficult to discern from the Complaint." *Id.* This requirement is especially important in cases with multiple defendants because if "particular misrepresentations are not specifically set out in the complaint, it is also difficult (if not impossible) to determine which of the [defendants] should be charged with these utterances." *Id.*

I. PLAINTIFF'S ANTITRUST CLAIMS (COUNTS I-II) AGAINST THE EXPRESS SCRIPTS ENTITIES SHOULD BE DISMISSED

A. Plaintiff Does Not Allege That Any Anticompetitive Conduct Was the Proximate Cause of Its Purported Overpayments

To state a valid TTPA claim, Plaintiff must allege that anticompetitive conduct was the proximate cause of its purported injury. *See Steamfitters Local Union No. 614 Health & Welfare Fund v. Philip Morris, Inc.*, No. W1999-01061-COA-R9-CV, 2000 WL 1390171, at *7 (Tenn. Ct. App. Sept. 26, 2000) (affirming dismissal of antitrust claim under TTPA because plaintiffs failed to show that defendants' "wrongful conduct proximately caused their injury" where plaintiffs' alleged injuries were "too remote, as a matter of law"); *see also Perry v. Am. Tobacco Co.*, 324 F.3d 845, 851 (6th Cir. 2003) ("The same proximate cause standard [as that used for federal antitrust and racketeering claims] governs . . . statutory claims under the TCPA and the TTPA.").

As in the Illinois Litigation, Plaintiff's antitrust claims should be dismissed because its purported overpayment for Acthar is too attenuated from the alleged anticompetitive conduct. *See City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 760-61 (N.D. Ill. 2019) (dismissing Plaintiff's claims—including its TTPA claim—against the Express Scripts Entities because "Acument would not meet even the least stringent state's 'proximate cause' test"). As Judge Kapala explained, Plaintiff's alleged injury is too remote because it did not plead that ESI was its PBM or that it had any other "purchasing relationship to [the] Express Scripts [Entities]." *Id.* at 752. Accordingly, Plaintiff failed to allege facts showing "how Acument's injuries in Tennessee are connected to [D]efendants' conduct." *Id.* at 760.

Here, the Complaint suffers from the same fatal flaw because Plaintiff's allegations establish that its reimbursements for Acthar are several steps removed from any alleged misconduct. While Plaintiff asserts that the purported conspiracy between Questcor and the

Express Scripts Entities caused ESI "not [to] push back against Questcor's decision to raise prices" (Compl. ¶ 358), Plaintiff fails to allege that its payments for Acthar were made to ESI or any other Express Scripts Entity, or that those entities had any impact on the amounts Plaintiff paid. To the contrary, the Complaint alleges that "Acument's payment was made to its PBM, CVS Caremark" (*id.* ¶ 98), a competitor of ESI. In addition, Plaintiff alleges that "[t]he Acument patient at issue dealt with CVS Caremark Specialty" (*id.*), a competitor of Accredo. Thus, Plaintiff provides no explanation as to how the alleged anticompetitive conspiracy—and ESI's purported failure to "push back" to negotiate lower Acthar prices for its clients—could be the proximate cause of Plaintiff's alleged overpayments for Acthar, given that Plaintiff was not a client of ESI or any other Express Scripts Entity. Accordingly, as in the Illinois Litigation, Plaintiff's TTPA claim should be dismissed for this reason alone.

B. Plaintiff Fails To Sufficiently Allege That the Express Scripts Entities Engaged in Any Anticompetitive Conduct

An essential element of a TTPA claim is that the challenged conduct harms competition. *See Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 522 (Tenn. 2005) ("[T]he *effect* of the anticompetitive conduct on Tennessee trade or commerce is determinative of whether the TTPA is applicable under the circumstances."); *see also Spahr v. Leegin Creative Leather Prods., Inc.*, No. 2:07-CV-187, 2008 WL 3914461, at *13-14 (E.D. Tenn. Aug. 20, 2008) (dismissing TTPA claim for failure to sufficiently allege agreement harmed competition). As a result, Plaintiff's failure to allege that the Express Scripts Entities engaged in any anticompetitive conduct is fatal to its TTPA claims.

Plaintiff asserts that two separate categories of alleged agreements between Mallinckrodt and individual Express Scripts Entities violate the TTPA. ***First***, Plaintiff asserts that agreements related to the distribution of Acthar—Mallinckrodt's exclusive distribution agreement with

CuraScript SD and its use of UBC as the "exclusive agent to operate the ASAP Program"—"prevent a competitive product from entering the market" and thus "allow Mallinckrodt to maintain and enhance its monopoly power in the ACTH market." (Compl. ¶¶ 335, 337.) ***Second***, unsupported by any factual allegations, Plaintiff asserts that ESI agreed with Mallinckrodt to fix the price of Acthar, which is "set by Mallinckrodt." (*Id.* ¶¶ 358-66.) As a matter of law, neither set of allegations is actionable.

1. Plaintiff Does Not Sufficiently Allege That the Agreements Related to the Distribution of Acthar Have Harmed Competition

Courts routinely dismiss antitrust claims challenging exclusive distribution agreements for lack of harm to competition.[4] Indeed, exclusive agreements between an alleged upstream monopolist—like Mallinckrodt—and a distributor generally cannot harm competition because they "provide[] no monopolistic benefit to [the monopolist] that it does not already enjoy and would not continue to enjoy" absent the exclusive agreement. *E & L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2d Cir. 2006). A monopolist can control its own pricing and output to the same extent regardless of the number of distributors it employs or its distribution method. *See id.* at 30 ("The power to restrict output to maximize profit is complete in the manufacturing monopoly, and there is no additional monopoly profit to be made by creating a monopoly in the retail distribution of the product."); *see also Byars v. Bluff City News Co.*, 609 F.2d 843, 861 (6th Cir. 1979) ("[T]here exists one profit-maximizing monopoly price to the consumer of any given

[4] *See, e.g.*, *E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n*, 357 F.3d 1, 8-9 (1st Cir. 2004) (affirming dismissal of complaint with prejudice because plaintiff "does not remotely suggest that so many potential outlets are foreclosed to it or other competitors by long-term exclusive dealing contracts or other tactics that survival or new entry is infeasible"); *Rutman Wine Co. v. E. & J. Gallo Winery*, 829 F.2d 729, 734-36 (9th Cir. 1987) ("[A]n agreement between a manufacturer and a distributor to establish an exclusive distributorship is not, standing alone, a violation of antitrust laws, and in most circumstances does not adversely affect competition in the market."); *VBR Tours, LLC v. Nat'l R.R. Passenger Corp.*, No. 14-CV-804, 2015 WL 5693735, at *12-13 (N.D. Ill. Sept. 28, 2015) (dismissing antitrust claim based on exclusive agreement between Amtrak and tour operator because Amtrak "could have accomplished the same effect by acquiring a tour operator or creating its own in-house tour operator").

product."). Accordingly, unless the exclusive distributorship prevents a competitor of the upstream monopolist from entering the market, there can be no harm to competition. *See Epic Sys. Corp. v. Tata Consultancy Servs. Ltd.*, No. 14-cv-748, 2017 WL 4386456, at *4 (W.D. Wis. Sept. 29, 2017) (to show anticompetitive effects from vertical agreement, plaintiff must sufficiently allege that "anti-competitive conduct 'is likely to keep at least one significant competitor . . . from doing business'" (ellipses in original) (citation omitted)).

Here, Plaintiff insufficiently alleges that the agreements between Mallinckrodt and the Express Scripts Entities have harmed competition.[5] To the contrary, the Complaint alleges that Mallinckrodt has maintained its ACTH monopoly through conduct independent of any agreement involving, or action taken by, an Express Scripts Entity. Specifically, Plaintiff alleges that Mallinckrodt has maintained its purported monopoly because of the difficulty of developing therapeutic ACTH drugs and receiving FDA approval (Compl. ¶¶ 235-37), the FDA's orphan drug designation (*see id.* ¶¶ 57, 234), and Questcor's acquisition of the rights to Synacthen and refusal to "bring this viable synthetic alternative to Acthar to market" (*id.* ¶¶ 191, 340-41). Plaintiff does not allege facts suggesting that any Express Scripts Entity was involved in—or "conspired" with Questcor or Mallinckrodt concerning—any of this conduct.[6]

[5] In the Illinois Litigation, the federal court mistakenly credited the plaintiffs' theories as to how the exclusive distribution agreements between Mallinckrodt and the Express Scripts Entities allegedly harmed competition, even though none of those theories is viable as a matter of well-settled law. *See Rockford*, 360 F. Supp. 3d at 749-51. Notably, the court only credited those theories to the extent it mistakenly concluded that the exclusive distribution agreements and Synacthen acquisition were part of the same conspiracy even though there was no allegation in the operative complaint that an Express Scripts Entity was involved in Questcor's acquisition of the Synacthen rights. *See id.* at 749, 756.

[6] When they sued Mallinckrodt, neither the FTC nor Retrophin brought any claim against an Express Scripts Entity. In fact, neither made any allegations regarding the distribution of Acthar or ASAP. (*See* Compl., Ex. D (FTC complaint), Ex. E (Retrophin complaint).)

Accordingly, the Complaint fails to sufficiently allege harm to competition resulting from any agreement involving an Express Scripts Entity and, therefore, Plaintiff's TTPA claims challenging these agreements should be dismissed.

2. Plaintiff Does Not Sufficiently Allege That the Express Scripts Entities and Mallinckrodt Conspired To Fix Prices for Acthar

Another element of Plaintiff's TTPA claims is concerted conduct, such as "arrangements, contracts, agreements, trusts, or combinations." Tenn. Code Ann. § 47-25-101 (prohibiting certain "arrangements, contracts, agreements, trusts, or combinations"); *see In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 415-16 (E.D. Pa. 2009) (dismissing TTPA claim "[b]ecause Plaintiffs' complaint did not allege that GSK acted in concert with any other party"). Factual allegations couched as legal conclusions (e.g., that defendants conspired) need not be accepted as true. *See West*, 468 S.W.3d at 489 ("[C]ourts are not required to accept as true assertions that are merely legal arguments, or legal conclusions, couched as facts." (citations omitted)).

Here, Plaintiff asserts that "Express Scripts conspired and agreed with Mallinckrodt to fix and charge artificially inflated prices for Acthar to CVS Caremark clients, like Acument" (Compl. ¶ 361),[7] and that CVS Caremark "simply charged the same . . . prices based on the prices set by Mallinckrodt in agreement with Express Scripts" (*id.* ¶ 360). But Plaintiff does not allege facts to suggest an agreement between any Express Scripts Entity and Mallinckrodt as to the prices Mallinckrodt charges for Acthar, or the reimbursement rate CVS Caremark charges to any of its clients, including Plaintiff. (*See id.* ¶¶ 359-61.)[8]

[7] It is not clear how Express Scripts, as a PBM, could have charged prices to the clients of another PBM, CVS Caremark, at all, let alone purportedly artificially inflated prices. Moreover, this allegation contradicts the allegation that CVS Caremark charged Plaintiff for its beneficiary's Acthar prescriptions.

[8] As noted above (*see supra* p. 11 n. 5), the federal court in the Illinois Litigation determined that the plaintiffs sufficiently alleged an antitrust conspiracy between Mallinckrodt and the Express Scripts Entities based on the *(cont'd)*

To the contrary, the Complaint repeatedly pleads facts illustrating that ***Mallinckrodt unilaterally*** sets the AWP for Acthar. (*See, e.g.*, *id.* ¶ 114 ("***Mallinckrodt raised the list price*** for Acthar, or the wholesale acquisition cost ('WAC'), to $748.16. ***It raised the end payor price***, or the average wholesale price ('AWP'), to $935.20." (emphases added)); *id.* ¶ 117 ("When ***Mallinckrodt*** implemented its new strategy on August 27, 2007, ***it raised the WAC*** for Acthar from $1,650.23 to $23,269.00. ***It also raised the AWP*** for Acthar from $2,062.79 to a staggering $29,086.25." (emphases added)); *id.* ¶ 271 ("***Mallinckrodt has raised*** the WAC multiple times, at least once a year. . . ." (emphasis added)).)

Moreover, Plaintiff alleges that Express Scripts "did not push back against ***[Mallinckrodt's] decision*** to raise prices" (*id.* ¶ 358 (emphasis added)), which is contrary to any assertion of an agreement between an Express Scripts Entity and Mallinckrodt.[9] Rather, those allegations are consistent with the Complaint's other allegations illustrating that Mallinckrodt unilaterally sets the price for Acthar. Accordingly, Plaintiff's theory that the Express Scripts Entities and Mallinckrodt conspired to fix prices for Acthar fails, and Plaintiff's TTPA claim should be dismissed.

(cont'd from previous page)
court's erroneous conclusion that plaintiffs alleged that the Express Scripts Entities somehow facilitated Questcor's acquisition of Synacthen.

[9] Plaintiff also fails to allege facts to support their inactionable and conclusory assertion that Express Scripts "did not push back against [Mallinckrodt's] decision to raise prices." (Compl. ¶ 358.) The Complaint speculates that Express Scripts could have "wield[ed] its market power" to halt Acthar price increases because it supposedly was successful in doing so for a different high-priced specialty drug, Daraprim. (*Id.* ¶ 356; *see also id.* ¶ 109.) But Plaintiff's own allegations concerning Daraprim are to the contrary. According to Plaintiff, Express Scripts did not "wield its market power" to cause the manufacturer of Daraprim to halt price increases. Rather, Express Scripts worked with another manufacturer to develop a low-cost alternative, which had the effect of reducing Daraprim prices. (*Id.* ¶¶ 109-10, 357.) In contrast, here, Plaintiff alleges that creating an alternative to Acthar is not feasible because of the difficulty of developing ACTH drugs and receiving FDA approval. (*See id.* ¶¶ 235-36.)

II. THE TENNESSEE CONSUMER PROTECTION ACT CLAIM (COUNT III) SHOULD BE DISMISSED

The elements of a TCPA claim are: "(1) that the defendant engaged in an unfair or deceptive act or practice declared unlawful by the TCPA and (2) that the defendant's conduct caused an 'ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated.'" *Berkley v. Deutsche Bank Nat'l Tr. Co.*, No. 2:12-cv-02642-JTF-cgc, 2013 WL 6834385, at *7 (W.D. Tenn. Dec. 20, 2013) (citations omitted). Plaintiff fails to sufficiently allege either of these elements.

A. Plaintiff Does Not Plead Facts Suggesting the Express Scripts Entities Engaged in an Unfair or Deceptive Act or Practice

Plaintiff's deficient TCPA claim is based on three types of purportedly deceptive statements, none of which sufficiently alleges an unfair or deceptive practice. ***First***, Plaintiff claims that Defendants failed to publicly disclose the purportedly anticompetitive agreements between Questcor or Mallinckrodt and the Express Scripts Entities. (*See* Compl. ¶ 376(a)-(f).) ***Second***, Plaintiff asserts that Defendants misrepresented the worth or value of Acthar and that ESI began offering discounts for Acthar only after it made statements in 2017 about Acthar being overpriced, without explaining why the discounts for Acthar were "far less than the discounts offered for either brands or generics." (*Id.* ¶ 376(f).) ***Third***, Plaintiff asserts that "[i]n their promotion of Acthar to treat diseases other than IS, like the [nephrotic syndrome] suffered by Acument's beneficiary, Defendants have disparaged the goods, services or business of other sellers of drugs that treat such diseases more effectively and safely, and for much less money, by false or misleading representations of fact." (*Id.* ¶ 376(g).)

1. Plaintiff Cannot Base Its TCPA Claim on an Alleged Failure To Disclose Purportedly Anticompetitive Conduct

In a thorough opinion that evaluates the text and legislative history of the TCPA, the Tennessee Court of Appeals held that "claims based upon anticompetitive conduct are not cognizable under the TCPA." *Sherwood v. Microsoft Corp.*, No. M2000-01850-COA-R9-CV, 2003 WL 21780975, at *33 (Tenn. Ct. App. July 31, 2003). The court reasoned that unlike the FTC Act, which prohibits both "unfair methods of competition" and "unfair or deceptive acts or practices," the TCPA prohibits only "unfair or deceptive acts or practices." *Id.* at *31 (citations omitted). "The choice was significant because federal courts 'interpreted the "unfair methods of competition" language as applying to violations of the Sherman Act and other antitrust statutes and to actions raising antitrust issues or concerns.'" *Bennett v. Visa U.S.A. Inc.*, 198 S.W.3d 747, 754 (Tenn. Ct. App. 2006) (quoting *Sherwood*, 2003 WL 21780975, at *31 n.35). Accordingly, the court concluded that it "cannot presume other than that the Tennessee General Assembly knowingly chose not to include antitrust or anticompetitive conduct as actionable under the TCPA," and TCPA "claims based on allegations of anticompetitive conduct must be dismissed." *Sherwood*, 2003 WL 21780975, at *32.

Since the Tennessee Court of Appeals issued the *Sherwood* decision, federal and Tennessee state courts have applied its holding to dismiss TCPA claims based on anticompetitive conduct. *See, e.g.*, *In re Photochromic Lens Antitrust Litig.*, No. 8:10-MD-2173-T-27EAJ, 2011 WL 4914997, at *4 & n.14 (M.D. Fla. Oct. 14, 2011); *PHG Techs., LLC v. St. John Cos.*, 459 F. Supp. 2d 640, 645 (M.D. Tenn. 2006); *Bennett*, 198 S.W.3d at 754.[10]

[10] The Tennessee Court of Appeals and federal courts have since followed *Sherwood* instead of *Blake v. Abbott Labs., Inc.*, No. 03A01-9509-CV-00307, 1996 WL 134947 (Tenn. Ct. App. Mar. 27, 1996)—which held that a TCPA claim could be based on anticompetitive conduct, *id.* at *5-7—because in *Blake* the court did not consider the statutory history recounted in *Sherwood* or "investigate the federal courts' interpretation of 'unfair or deceptive acts or practices' as required by § 47-18-115." *Bennett*, 198 S.W.3d at 753-54.

Plaintiff's TCPA claim should be dismissed to the extent it is based on statements relating to the exclusive distribution of Acthar, UBC's operation of ASAP, or some sort of other purported antitrust conspiracy between the Express Scripts Entities and Questcor or Mallinckrodt. (*See* Compl. ¶ 376(a)-(f).) The essence of these allegations is that Defendants engaged in secret conduct that Plaintiff asserts is anticompetitive, which could not constitute an unfair or deceptive act or practice under the TCPA even if Plaintiff had stated a valid TTPA claim (which it has not).[11]

Moreover, contrary to Plaintiff's assertion that Defendants concealed the exclusive distribution agreement between Questcor and CuraScript SD or UBC's operation of ASAP, Plaintiff's own allegations and the exhibits it attached to the Complaint highlight that Defendants ***publicly disclosed*** these arrangements. (*See* Compl. ¶ 81 (alleging that patients sign a form that authorizes "'Mallinckrodt reimbursement support personnel ***and United BioSource Corporation ("UBC")***' . . . to provide Acthar and receive payment, among other things" (emphasis added) (quoting Compl. Ex. A)); *id.* Ex. B (Mallinckrodt "Urgent Product Alert," dated July 2, 2007, stating that "***[e]ffective August 1, 2007, Acthar Gel . . . will be available exclusively through Specialty Pharmacy Distribution***" and that "[b]eginning July 16, 2007, hospitals should place all stock orders with CuraScript [SD]" (emphasis in original)).)

[11] Even if Plaintiff had stated a claim under the TTPA—based on CuraScript SD's exclusive distribution of Acthar, UBC's operation of ASAP, or some sort of other conspiracy between the Express Scripts Entities and Questcor or Mallinckrodt—Defendants' purportedly anticompetitive conduct would be the cause of Plaintiff paying inflated prices, not statements concerning or hiding that conduct. *See In re New Motor Vehicles Canadian Export Antitrust Litig.*, 350 F. Supp. 2d 160, 177 (D. Me. 2004) ("[E]ven if an American dealer had said to consumer, 'You know, this car costs more because we have conspired with the manufacturers to prevent Canadian cars from coming into the American market,' the price would have remained the same (unless and until someone halted the alleged conspiracy)."). Accordingly, a TCPA claim based on purportedly deceptive acts in hiding allegedly anticompetitive conduct would fail for lack of causation.

2. Plaintiff Does Not Allege Deceptive Conduct Related to Statements About Discounts or Acthar's Worth or Value

Plaintiff alleges that ESI "misled Plaintiff and deceived Plaintiff about its approval of Acthar and the benefits of Acthar as a valuable specialty drug 'worth' what" Plaintiff was being charged (Compl. ¶ 376(e)), and that ESI began offering discounts for Acthar only after it made statements in 2017 about Acthar being overpriced, without explaining why the discounts for Acthar were "far less than the discounts offered for either brands or generics" (*id.* ¶ 376(f)).

These conclusory allegations do not meet the heightened pleading standard of Rule 9.02. Indeed, Plaintiff does not allege that any Express Scripts Entity made any statement about "its approval of Acthar," the "benefits of Acthar," Acthar's "worth" or "value," or "discounts offered for either brands or generics" (*id.* ¶ 376(e), (f))—other than a statement in 2017 that Acthar was overpriced by Mallinckrodt (*see id.* ¶¶ 163-64).[12] And even if the Express Scripts Entities made no public statements before 2017 about Acthar being overpriced, that silence cannot be deceptive unless they made some contradictory statement, such as a statement that the AWPs for Acthar were worth the value that the drug provided. Plaintiff has alleged no such statement.

Moreover, Plaintiff's allegation that the Express Scripts Entities only began to offer discounts for Acthar beginning in 2017 (*id.* ¶ 376(f)) appears to have been inadvertently copied from a different complaint filed by Plaintiff's counsel because Plaintiff does not allege that it

[12] Although not alleged in the TCPA count, Plaintiff also appears to fault ESI for purportedly waiting until 2018 to institute a prior authorization policy for its clients that excluded from coverage prescriptions for nephrotic syndrome. (*See* Compl. ¶¶ 174-75.) Even if it were included in the TCPA count, this theory would fail to identify an actionable misrepresentation because Plaintiff was not an ESI client and thus would not have been aware of ESI's prior authorization policies (nor does Plaintiff allege it in fact was aware of ESI's prior authorization policies before deciding to reimburse for Acthar). Moreover, contrary to the allegations in the Complaint (and as Plaintiff's counsel should know from discovery in the Illinois Litigation), since 2012, ESI's prior authorization policy for Acthar has excluded from coverage all uses for Acthar other than infantile spasms and multiple sclerosis flares.

reimbursed for an Acthar prescription after 2016.[13] And Plaintiff's factual allegations suggest it would not have received any discount from any Express Scripts Entity—or any Defendant—because it does not allege it ever dealt with any Express Scripts Entity—or any Defendant—in reimbursing its beneficiary's Acthar prescriptions. Rather, Plaintiff alleges it paid its PBM, CVS Caremark, for its beneficiary's Acthar prescriptions. (*Id.* ¶ 98.)

Thus, Plaintiff does not sufficiently allege deceptive conduct related to statements about discounts or Acthar's worth or value, and the TCPA claim should be dismissed to the extent it is based on such purported statements.

3. Plaintiff Does Not Allege Any Statement Disparaging the Goods, Services, or Business of Other Suppliers of Drugs

Finally, Plaintiff asserts that "[i]n their promotion of Acthar to treat diseases other than IS, like the [nephrotic syndrome] suffered by Acument's beneficiary, Defendants have disparaged the goods, services or business of other sellers of drugs that treat such diseases more effectively and safely, and for much less money, by false or misleading representations of fact." (Compl. ¶ 376(g).) Presumably, this allegation concerns Tenn. Code Ann. § 47-18-104(b)(8), which declares that unfair or deceptive acts or practices include "[d]isparaging the goods, services or business of another by false or misleading representations of fact." Tenn. Code Ann. § 47-18-104(b)(8).

However, Plaintiff cannot base its TCPA claim on Section 47-18-104(b)(8) because the Complaint does not allege any statement by any Defendant disparaging other medications, much less with the particularity required by Rule 9.02. *See Quality Auto Parts Co. v. Bluff City Buick Co.*, 876 S.W.2d 818, 822 (Tenn. 1994) (affirming dismissal of claim under Section 47-18-

[13] Paragraph 376(e) also includes a reference to a Pennsylvania statute. (*See* Compl. ¶ 376(e) (citing "73 Pa. Stat. Ann. §§201").)

104(b)(8) because "the statements did not criticize or disparage the quality of [plaintiff's] services as a parts manager").

For all of the above reasons, Plaintiff has not sufficiently alleged an unfair or deceptive act or practice, and its TCPA claim should be dismissed.

B. Plaintiff Does Not Plead Facts Suggesting That Any Purportedly Deceptive Conduct Caused It Harm

In addition to failing to adequately allege an unfair or deceptive trade practice, Plaintiff does not sufficiently allege that any purportedly unlawful conduct caused it harm. ***First***, as Judge Kapala held, any purported harm to Plaintiff is too attenuated from the alleged wrongdoing to be actionable under any state consumer protection statute. *Rockford*, 360 F. Supp. 3d at 760. (*See also supra* pp. 8-9.) Accordingly, Plaintiff's TCPA claim should be dismissed for this independent reason.

Second, Plaintiff does not allege that it read, heard, or was otherwise aware of any purported misrepresentation by an Express Scripts Entity. Thus, Plaintiff cannot have relied on any such statement in deciding to reimburse for Acthar, and its TCPA claim also should be dismissed for this reason alone. *See Harvey v. Ford Motor Credit Co.*, 8 S.W.3d 273, 276 (Tenn. Ct. App. 1999) (affirming dismissal of TCPA claim because "[n]owhere in the Amended Complaint, however, does the appellant allege that he ever saw or heard any of these advertisements," and "plaintiffs must at least allege that they were exposed to the offensive conduct").

III. THE FRAUD CLAIM (COUNT V) SHOULD BE DISMISSED

> In order to establish a claim for fraudulent or intentional misrepresentation, a plaintiff must show the following: (1) the defendant made a representation of an existing or past fact; (2) the representation was false when made; (3) the representation was in regard to a material fact; (4) the false representation was made either knowingly or without belief in its truth or recklessly; (5) plaintiff

> reasonably relied on the misrepresented fact; and (6) plaintiff suffered damage as a result of the misrepresentation.

PNC Multifamily, 387 S.W.3d at 548. Plaintiff has failed to sufficiently allege several elements of its fraud claim.

A. Plaintiff Does Not Plead Facts Suggesting a Misrepresentation With Sufficient Particularity

Plaintiff insufficiently alleges that "Defendants made material misrepresentations that those prices represented the purported 'average' of 'wholesale prices' for Acthar, or some price reasonably related thereto, which they did not. Defendants also misrepresented that the inflated AWP prices for Acthar represented the actual value of the product in the marketplace, which they did not." (Compl. ¶ 391.) As Judge Kapala held concerning substantively identical allegations in the Illinois Litigation, Plaintiff's fraud claim should be dismissed because it is insufficiently particular. *See Rockford*, 360 F. Supp. 3d at 776-77 (dismissing fraud claim for lack of particularity because "plaintiffs offer general allegations that because the 'prices [for Acthar] were artificial prices,' '[d]efendants made material misrepresentations that those prices represented a calculation of real and fact-based prices for their drugs, and that they represented the actual value of the product in the marketplace'" (alterations in original) (citations omitted)).

Fatal to Plaintiff's fraud claim, the Complaint fails to identify any particular false statement, who made it, or when or to whom it was made. *See PNC Multifamily*, 387 S.W.3d at 549 (affirming dismissal of complaint because it did not allege "what representations were made and by whom" and "[t]he exact misrepresentation(s) . . . are difficult to discern from the Complaint"). Instead, Plaintiff makes vague and conclusory allegations about the price of Acthar that are devoid of particularity or factual support. Indeed, the Complaint does not identify any specific statement by any Express Scripts Entity—or any other Defendant—

regarding the price of Acthar being the "'average' of 'wholesale prices'" or representing "the actual value of the product in the marketplace." (Compl. ¶ 391.) Moreover, that the price of Acthar was allegedly "inflated" does not render that price "false." *See Thompson's Gas & Elec. Serv., Inc. v. BP Am. Inc.*, 691 F. Supp. 2d 860, 870 (N.D. Ill. 2010) ("The fact that Defendants were offering propane for sale at inflated prices does not mean those prices were somehow 'false.'"). Thus, Plaintiff's generalized allegations cannot sustain its fraud claim.

B. Plaintiff Does Not Plead Facts Suggesting That It Relied on Any Purported Misrepresentation to Its Detriment

As with its TCPA claim, Plaintiff fails to sufficiently allege damages resulting from its reliance on any purportedly false statement because Plaintiff does not allege that it read, heard, or was otherwise aware of any purported misrepresentation by an Express Scripts Entity. (*See supra* p. 19.) Accordingly, Plaintiff's fraud claim also should be dismissed for this independent reason. *See Wigley v. Am. Equity Mortg.*, No. 15-CV-2473, 2016 WL 866359, at *5 (W.D. Tenn. Mar. 3, 2016) (dismissing fraud claim because the complaint "fails to allege how Plaintiffs relied on the misrepresentation").

IV. THE UNJUST ENRICHMENT (COUNT IV) AND CONSPIRACY TO DEFRAUD (COUNT VI) CLAIMS SHOULD BE DISMISSED

Plaintiff's unjust enrichment and conspiracy to defraud claims require that its claims for the torts underlying these causes of action be sufficiently pled. *See Marshall v. ESPN Inc.*, 111 F. Supp. 3d 815, 837 (M.D. Tenn. 2015) (dismissing unjust enrichment claim because it was premised on same purportedly unlawful conduct as antitrust and other claims that were dismissed), *aff'd* 668 F. App'x 155 (6th Cir. 2016); *Kincaid v. SouthTrust Bank*, 221 S.W.3d 32, 38 (Tenn. Ct. App. 2006) (claim for civil conspiracy requires an overt act of fraud in furtherance of the conspiracy).

Here, Plaintiff's unjust enrichment and conspiracy to defraud claims should be dismissed because they rely on the same alleged misconduct as Plaintiff's deficient TTPA, TCPA, and fraud claims. Specifically, the unjust enrichment and conspiracy to defraud claims are based on "a continuing conspiracy to defraud and deceive Acument by causing them [*sic*] to pay more for Acthar than they [*sic*] otherwise would have paid in the absence of the Defendants' conspiracy and concerted action." (Compl. ¶ 400 (conspiracy to defraud claim); *see also id.* ¶ 387 (in unjust enrichment claim, stating, Defendants "were able to extract exorbitant revenue from Acument beyond what they could have received in the absence of such unlawful conduct").) Thus, these claims should be dismissed because Plaintiff has not alleged a viable claim under the TTPA or TCPA or for fraud.

Plaintiff's unjust enrichment claim also fails for the independent reason that Plaintiff does not allege it has exhausted any remedy it may have against CVS Caremark—the entity with which it has a contract—or that such exhaustion would have been futile. "Tennessee law dictates that a plaintiff seeking relief for unjust enrichment must demonstrate that he 'exhausted all remedies against the person with whom the plaintiff enjoyed privity of contract.'" *Rockford*, 360 F. Supp. 3d at 772 (quoting *Spahr*, 2008 WL 3914461, at *14). Indeed, Judge Kapala dismissed Plaintiff's unjust enrichment claim for this very reason, holding: "Acument does not allege that it has exhausted any remedies against CVS. This is fatal to Acument's [unjust enrichment] claim." *Id.* Because Plaintiff has not remedied this defect in its complaint (*see* Compl. ¶¶ 381-88), its unjust enrichment claim fails for this independent reason.

CONCLUSION

For the foregoing reasons, all claims against the Express Scripts Entities should be dismissed.

Dated: July 23, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been delivered via U.S. mail this 23rd day of July 2019, to the following:

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